THE EXPANDED PROGRAMME

ON

IMMUNIZATION

COMPENDIUM OF TECHNICAL PAPERS

DIRECTORATE OF HEALTH SERVICES
MAHARASHTRA STATE, PUNE
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IMMUNIZATION

A COMPENDIUM OF TECHNICAL PAPERS FOR TRAINING OF KEY PERSONNEL

DIRECTORATE OF HEALTH SERVICES
MAHARASHTRA
PUNE

PUBLICATION BOARD

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FORWARD :

Immunizations against communicable diseases have been in vogue since Edward Jennar discovered Smallpox Vaccine in 1799. However, it took more than 150 years to eradicate smallpox from this country and may be probably from the world.

To-day we have potent vaccines available against Diptheria, Pertussia, Tetanus, Typhoid, Polionyelitie, Tuberculosis etc. By adopting a proper and systematic immunization programme we will be able to control all these diseases if not eradicate them like smallpox.

These diseases were big killers of human lives in the past and still continue to threaten mankind. It is very heartening to mention that in our country and State, massivo immunization programme covering various population groupe in general and mothers and children in particular are being launched. World Health Organization is providing active help and assistance in implemenuation of these programmes especially its training aspects. The circle and district officers of health services will be initially trained and they in turn will provide further training to the P.H.C. Medical Officer and peripheral health staff.

It gives me immense pleasure to publish the compendium of technical papers which will serve as a background document for this training. I wish to convey my sincerest thanks to the W.H.O. for this publication. I am confident that this programme will succeded and our people will be more healthy and prosperous.

Dr.V.V.KAYARKAR
DIRECTOR
HEALTH SERVICES (M.S.) BOMBAY.

5th April 1978.

CONTENTS

INTRODUCTION TO THE EPI

Each year more than 80,000,000 children are born in the developing world. Approximately 5,000,000 of them die from tetanus, whooping cough, diphtheria or poliomyelitis.

Less than 10% of the newborn, however, receive immunization against these diseases and fewer than 5% receive potent measles vaccine.

In addition to those who die, at least twice as many are disabled through brain damage, paralysis, stunted growth, deafness and blindness.

None of this should happen. Children can be protected against all these diseases. There are safe vaccines available. The vaccines for the six diseases together cost little more than US $1, to protect each child in the developing world for life.

Vaccine against diphtheria and tetanus can provide life-long immunity to over 95% of those inoculated.

Vaccine against whooping cough (pertussis), gives up to 80% protection in the face of the strongest exposure.

One dose of BCG gives almost complete protection against childhood tuberculosis.

The complete course of three doses of polio vaccine gives long-lasting immunity with over 95% protection.

One dose of the live vaccine against measles gives 95% protection for at least 15 years, and probably for life.

To assist governments in expanding or establishing immunization programmes, WHO at the request of the World Health Assembly has launched the Expanded Programme on Immunization.

The expanded Programme on Immunization has its basis in resolution WHA 27.57, adopted by the World Health Assembly in May 1974. In brief, this resolution called on Member States to ".....develop or maintain immunization and surveillance programmes against some or all of the following diseases : diphtheria, pertussis, tetanus, measles, poliomyelitis, tuberculosis, smallpox and others, where applicable.....", and requested WHO, among other activities, to collaborate closely with governments in developing their programmes, in mobilizing all efforts to make available quality vaccines and other equipment and supplies to meet country needs, to support educational and research activities and to establish a special account under the Voluntary Fund for Health Promotion.

The ultimate goal is to provide immunization against these diseases to every child in the world by 1990.

Resolution WHA 30.53 adopted on 19 May 1977; approved the programme objectives and general policies presented by the Director-General. In the same resolution, the World Health Assembly recommended that Member States formulate specific plans for the development or maintenance of immunization activities on a long-term basis. and urged governments and appropriate scientific institutions to intensify scientific research in respect of development of better and more stable vaccines and improving vaccination techniques. Resolution WHA 30.54, adopted on the same date, draws attention to the importance of promoting regional and national self-reliance for vaccine production.

The main objective of the programme is to reduce morbidity and mortality from the diseases listed above by immunizing the maximum number of children below three years of age and expectant mothers in preventing tetanus neonatorum.

Most of the countries already have immunization programmes.

Therefore the basic strategy of the Expanded Programme on Immunization is step by step expansion of the immunization in three directions :

—geographically, by adding new areas,

—technologically, by adding more complex vaccines requiring special handling,

—socially, by including new segments of the population.

The expansion is usualiy determined by several factors, particularly availability of staff, vaccines and logistics.

On the other hand, since the vaccines are available against six diseases, the priorities in technical expansion should also be determined.

In parts of the developing world, diphtheria, for example, is still a rare disease because immunity is developed early from diphtheritic skin infections. Incidence, however, is increasing with urbanization.

Recently, Dr. Prema Bali has reported at a symposium on diphtheria in Delhi, " ...that out of 208 cases admitted in the ID hospital during 1975, 8% were patients with diphtheria. Does it indicate how big is the problem of diphtheria in Delhi ? Probably not. This question is going to be answered by New Delhi Municipal Committee which is developing on going surveillance.

According to a WHO Weekly Epidemic Report, 9206 cases of poliomyelitis were reported in India during 1976. Is that a true figure of poliomyelitis incidence in the country ?

A limited survey in 22 municipal areas of Andhra Pradesh carried out In 1976, has revealed that 1.8 persons per thousand population are suffering from polio residual—paralysis. If one extrapolates it to the country's total population, more than 25,000 cases of polio with residual paralysis should be expected to occur yearly.

The age distribution of the paralysis cases indicates that the problem is gradually increasing. Polio-paralysis was found only in 0·04 per thousand among adults. This rate increases to 4 per thousand at the age of 10– 14 years and 4.5 among children of 0—4 years age group. The figures indicate that the problem in the municipal areas is gradually growing.

A survey among children attending schools in Rangoon revealed that 20 per thousand had paralytic disabilities typical of those of poliomyelitis a rate higher than in the United States in its prevaccination period. A similar survey in Ghana showed 7 per thousand. In contrast, a survey in Central Java indicated only 9 polio paralytic cases per million population.

How big this problem is in rural India can be determined only by comprehensive surveillance.

The Smallpox Eradication project in Bangladesh carried out a survey on natality and mortality rates in rural Bangladesh from December 1975 to February 1977. The diseases preventable by immunization were included in the survey. The results were arranged in a sequence to show the nine main causes of death. The survey indicates that 19.9 per cent of all deaths among children below 5 years were caused by diarrhoeal diseases, 18·1 by tetanus, 15.1 by pneumonia. Six other diseases share 3 to 8 per cent of mortality. Apart from tetanus, neither of the preventable diseases was found to be in the list of the 9 main killers. On the basis of this survey, the Government of Bangladesh has determined to expand the programme to respond to the main challenge—80% of the pregnant mothers will be immunized by tetanus toxoid from the year 1979 onward.

I hope these examples are convincing that epidemiological surveillance should become a built-in-element of the programme from the very beginning of implementation ofthe EPI.

WORLD HEALTH ORGANISATION
WHO EXPANDED PROGRAMME ON IMMUNIZATION

All children can be protected against Diptheria, Whooping cough, Tetanus, Poliomyelitis Measles and Tuberculosis

Each year more than 80 million children are born in the developing world and each year about five million die from these common contagious childhood diseases because less than 10% are protected through immunization. This does not occur in developed countries, where protection is provided before the first birthday.

In addition to those who die, many are disabled through brain demage, paralysis, stunted growth, chronic lung illnesses, deafness, blindness, measles and whooping cough can also prevent a child from eating and therefore push children into acute clinical malnutrition.

None of this should happen. Children can be protected against all these diseases. There are safe vaccines available. The vaccines for the six diseases together cost little more than US$ 1. - to protect each child in the developing world for life.

A healthy population is necessary for socio-economic development.

To assist governments in expanding or establishing immunization programme, WHO at the request of the World Health Assembly 1974, has launched the WHO Expanded Programme of Immunization.

WHO needs help to help these children.

Who expanded Programme on Immunization

Objective :—To collaborate with countries in strengthening and expanding their health services so that they can protect their children by immunization.

Target .—All children under the age of three, especially in the rural population and among the urban poor.

Vaccines*—Against *Diphtheria and Tetanus*, toxoids can provide life-long immunity to over 95% of those inoculated ;

—Against *Whooping cough* (*Pertussis*), a potent vaccine gives up to 80% protection in the face of the strongest exposure;

—Against childhood *Tuberculosis*, one dose of BCG, gives almost complete protection;

—Against *Polio* the complete course of three doses gives long-lasting immunity with over 95% protection;

—Against *Measles* one dose of the live vaccine gives 95% protection for at least 15 years, and probably for life. All vaccines used in the programme will meet the quality production standards and follow the potency and dosage level recommended by WHO Expert Committees.

Overall Strategy:—Commitment to the programme by every country involved is an essential prerequisite. There must be a determined and irreversible decision to extent the benefits of immunization to the bulk of the child population as a permanent service, backed up by funds from the national budget.

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*Vaccines against smallpox will not be included in this programme because of the success of the WHO smallpox eradication progamme which has helped to bring this disease to the point of no return. However, this does not prevent countries from including smallpox vaccination in their programme if local circumstances warrant this.

For long-term operational and financia feasibility, on-going immunization of children should be carried out by basic health workers as a routine part of existing health services if possible within maternal and child care services. Immunization services will expand only as fast and as far as the basic health services are expanded. The two are intrinsically linked.

The basic strategy is therefore a step-by-tested-step approach. The programme will be developed geographically by adding new areas, technologically by adding more complex vaccine requiring special handling, and socially by including the poorest segments of the population.

Only in this way can viable programme be built up and consolidated.

The biggest stumbling blocks to successful immunization programme are not medical or technical, but the practical difficulties arising from field operations. Supervision, administration, cooperation of the public, maintenance of transport and fuel supply, keeping the vaccines safe and effective through refrigeration from manufacturer to child, 'cold-chains', evaluation, monitoring—these are the problems.

The training and development of national skills and talents in operational, managerial and administrative problem-solving are also important.

Only in this way can these programmes become truly national.

Country strategy:—Most countries already have elements of an immunization programme which can be successfully expanded only if the programme becomes a national priority with government commitment to provide managerial manpower and funds.

Once these basic provisions have been met, WHO is cooperation with bilateral and multilateral aid agencies, can begin to work in partnership with each country and a programme based on each country's needs can be designed and implemented.

To establish a successful national programme each country must :

—Decide on objectives in terms of numbers of deaths and illnesses to be prevented for each diseases ;

—Determine if preliminary feasibility studies are needed;

—Plan alternative operational strategies, working out the extra unit costs (cost for each fully immunized child) for each strategy ;

--Determine the nature of external assistance needed ; work out costs to be borne by the national governments and the assisting agencies ;

—Estimate recurrent costs to be national budget of a continuous permanent programme;

—Strengthen delivery mechanisms to obtain cost effective coverage;

—Develop management, supply and refrigeration systems;

—Establish systems for monitoring and evaluating coverage and effectiveness ;

—Fix a step-by-step timetable for all stages of the programme including re-training, if necessary of supervisory staff and health workers.

WHO is ready to give its technical support in any or all of these areas. In addition to medical officers, WHO can provide field development officers with valuable experience gained in the worldwide smallpox eradication compaign. WHO can also help to establish facilities for quality control of vaccines and vaccine production. WHO is already, with billateral assistance, supporting research, to improve vaccine potency and effectiveness, developing vaccines against other diseases and improve the safety of the cold-chain in tropical countries.

Helping countries to develop their own capabilities in management and technology, strengthen and expand their health services, means that more people of all ages can have access to preventive and curative care,

External assistance :—The bulk of a country's needs will be met from its own resources. Even in well organized and implemented programmes, however, outside aid will be required for up to 5 to 10 years. Estimated budget summaries for 1976—80 are available.

Once needs have been clearly defined in carefully planned programmes, assistance can be given by aid agencies either on a *bilateral* or *multilateral* basis :—by direct contributions to individual countries for specific components of their programmes; by contributions to WHO itself as support to the overall programmes. Aid can take the form of cash, personnel, supplies etc.

External assistance is essential to meet the following needs.

—*Training* of all levels of national health workers, preferably within the country itself under actual field conditions.

—*Vaccines*:—For a fixed number of years.

—Transport for supplies and supervisory personnel. Transport costs (including fuel) are now the largest item of all rural immunization costs.

—*Cold-chain* and other equipment. If capital costs are met from external sources, recurrent and replacement costs can be met by national budgets.

—*Vaccine production/bottling* and *potency testing* through the establishment and strengthening of national or regional facilities taking into account the local level of microbiological technology and the size of the programme.

—*Funding of international field staff*, International project staff, medical officers and field development officers, will be needed for the initial stage until national supervisors take over. International staff will also be required at regional and headquarters level for supervision, administration and evaluation.

WHO is prepared to work with all donor agencies—UNICEF and UNDP are already involved—to make contributions more productive and joint participation more effective. WHO considers itself accountable to both donors and governments and will ensure that regular reports on the programme and use of contributions are issued. WHO will sponsor an annual meeting in Geneva of national programme managers, its own responsible officers, as well as representatives of all agencies assisting expanded immunization programmes for a joint review and evaluation.

Futher information is available from WHO Headquarters and Regional Offices

Functions of E.P.I. Section at the Directorate General of Health Services

1. Lay down precisely the objectives of the immunization programme and prepare a time-table for its implementation;

2. Analyse the present situation, viz. incidence of disease and current immunization activities and formulate the strategy and priority;

3. Ensure implementation of an integrated programme with the existing delivery system, viz. PHCs and sub-centres in the rural areas and hospitals and dispensaries in the urban areas;

4. Ensure training and supervision of staff in the field. Training of 30,000 smallpox staff are being organised to take up now assignment multi-purpose workers including E.P.I. with the financial assistance from WHO/SIDA. These additional staff will be placed at the disposal of the present implementing agencies such as MCH programme, Tuberculosis programme etc. for helping to achieve a better and bigger coverage then as at present;

5. Ensure production, procurement and distribution of quality vaccine. In this regard, look after at this Directorate the work relating to C.R.I., Kasauli, Pasteur Institute, Coonoor, Haffkine Institute, Bombay etc. Provide technical and administrative guidance to the vaccine manufacturing Institutes so that production of quality vaecine is maintained ;

6. Supply of materials and equipments like vaccines, cold storage facilities and other equipments to the states, and Develop cold chain for transport and storage of vaccines:

7. Establish liaison with the State Governments to promote immunization activities; Encourage institutions to make pilot projects, local studies, limited surveys to identify problems of the programme, develop innovations, evaluate vaccine coverage and surveillance of target diseases:

8. Undertake periodic assessment of the ongoing programme;

Develop a system of recording and reporting of target disease and vaccination performances and use these data in monitoring and modifying the programme.

Publish quarterly surveillance bulleting from the Centre.

9. Maintain technical liaison with International agencies like W.H.O., UNICEF, UNDP etc to frame proposals and utilize effectively the assistance provided for the programme;

10. Provide technical and administrative services to the Working Committee for the Execution of the Integrated Immunization Programme and the vaccine Production Board constituted by the Department of Health and to any other task force as may be required from time to time;

Terms of Reference of the Working Committee for the Execution of Integrated Immunization Programme at the Centre

1. To fix the annual target of coverage of mothers and children under the immunization programme.

2. To frame immunization schedules and undertake periodic review of the same.

3. To review the progress of the programme both at the Central and State level.

4. To lay down the methodology of evaluation of the technical aspects of the immunization programme through serological survey, scar survey, storage and distribution.

5. To supervise the orientation training programme at the State and Central level.

6. To undertake field visits to verify the actual implementation of the immunization programme.

7. To prepare annual report for submission to the Ministry of Health and Family Welfare about the progress and problems of the programme.

Immunization Schedule

Right from the birth children are exposen to various health hazards including communicable diseases. The natural resistance of the body to fight disease is of low order with the result that children fall on easy pray to diseases.

Immunization builds up the resistance of defence machanism in the children and this enables the body to fight and overcome infections.

A child needs to the protected against infections through immunization. Immunization should be done early in life and repeated periodically.

SCHEDULE OF VACCINATIONS

Age	Vaccination	
Pre-natal		
16—20 weeks	Tetanus toxide	1st dose
20—24 weeks	do.	2nd dose
36—38 weeks	do.	3rd dose
Children		
3—9 months	Small-pox vaccine B.C.G. Vaccine Diphtheria-pertusis-Tetanus (Triple vaccine) 3 dose at an interval of 1-2 months. Polio (trivalent oral vaccine) 3 doses at an interval of 1-2 months.	
9—12 months	Measles vaccine : one dose	
18—24 months	Diphtheria-pertusis-tetanus (triple vaccine) Booster dose. Polio (trivalent oral vaccine) Booster dose.	
5—6 years (school entry)	Diphtheria-tetanus (bivalent vaccine Booster dose. Typhoid (Monovalent or bivalent vaccine) one dose. After in interval of 1-2 months the typhoid vaccine one dose.	
10 years	Tetanus Toxide Booster dose. Typhoid (monovalent or bivalent vaccine) Booster dose.	
16 years	Tetanus Toxoid booster dose. Typhoid (monovalent or bivalent vaccine) Booster dose.	

Pre-natal ; When mothers are registered late in pregnancy at least two doses of tetanus toxoid should be given. For a mother who has been immunised, one booster dose of tetanus toxoid should be given in subsequent pregnancy preferably four weeks before the expected date of delivery.

Children : Ages indicated are considered to be the best times. However if there is any delay in starting the first dose of triple vaccine the ages may be adjusted accordingly. It should be the aim to ensure that a child receives small-pox, BCG, DPT and Polio-vaccination, where available, before it reaches one year of age. The different vaccines indicated against the various age groups can be given simultaneously : example BCG Tripple vaccine and Polio Vaccine, smallpox, Triple vaccine and Polio: etc.

When typhoid vaccine is being given for the first time two doses at an interval of 1-2 months require to be given,

E. P. I. Seminar Budget for the Retraining of N.S.E.P. Staff

1. **Training at State level for Chief Medical Officers/Dy. Chief Medical Officers and Regional Officers**

Period of Training : Max. 5 days

Actual Travel Expense (as per State Govt. rules) and Rs. 50 per diem for each participant.

The rate for CMOH/Dy. CMOH whose headquarter is same as that of training place is Rs. 20/- per day.

2. **Training at District level for PHC doctors and NSEP Staff**

Period of training– Max. 2 days

PHC Doctors : Actual Travel expense (as per State Govt. rules) and Rs.25/- per diem for each participant. The rate of PHC doctor whose headquarter is same as the training place will be Rs. 10/– per day.

NSEP staff : Actual Travel Expense (as per state Govt. rules) and Rs. 75/– as stipend for the total period of training at district level and in the field.

3. **Contingency :** Ceiling of 10% of the above budget for training materials and other petty expenditure.

Training And Execution of The Expanded Programme on Immunization

1. Committment by Government to implement a permanent immunization programme has to be obtained. The programme has to be included in Five Year Plan and budget provision has to be made.

2. E.P.I. Unit with a full time programme officer has to be established at the State Health Directorate.

3. Working Committee to co-ordinate and review the progress of the programme has to be constituted.

4. Analysis of the present disease incidence and inventory of current immunization activities has to be made.

5. The objectives of the programme have to be defined and time-table for implementation of the various activities has to be formulated.

6. Priority has to be selected in respect of area to be covered, disease to be tackled, infra-structure to be developed.

7. Plan of action to achieve the set operational target has to be devised. How the immunization Services will be delivered and by whom ? Phasing of the Programme has to be done. Details for 1978-79 have to be worked out.

8. Job–Description of the staff has to be written up and their training/orientation has to be arranged.

9. Supply system has to be developed, which will include procurement and distribution of vaccine and other equipments.

10. Reports and returns, their periodicaly and channel of transmission have to be specified.

COLD CHAIN SYSTEM IN THE SUPPLY AND DISTRIBUTION OF VACCINES

Summary :—There exists a cold range of temperature within which a vaccine keeps its full potency. Of the alternative sources for production of cold there is a need to develop one that is convenient for field operation in tropical developing countries. The operation of a cold chain is a matter of organization and co-ordination in management and requires supervision and control to be effective.

CHAPTER I

Temperature life of vaccines—Each vaccine has a clear time temperature life. Which varies with the type of vaccine longest with lypholized inactivated and toxoid vaccine and short with liquid live vaccines. Temperature life also varies according to the temperature at which the vaccine is kept; in general and within a certain cold range the lower the temperature the longer the life of the vaccine.

Viral vaccines are cryo resistant and keep well at low temperature below freezing such as —20° and —70° C. This is not the case with bacterial vaccines which are irreparably damaged once they are thawed. Bacterial vaccines liquid or freeze dried such as DPT, toxoid, typhoid, and cholera should be kept at 4°—8° C.

In general viral, bacterial and toxoid vaccines keep their potency well for upto 1—3 months if stored at refrigerator temperature namely 2° to 10° C.

One should recall that in summer time and particularly in tropical countries the temperature inside the cabinet of a refrigerator may be above 10° C during the day; hence the need to keep polio and measles in the freezer compartment. Annexure I gives a schedule of expected life of a vaccine and temperature that is recommended for short and medium storage.

CHAPTER II

Alternatives sources for cold

Principles in Physics to remember

1. **Newton's Law of cooling** (Col/Unit time)

Mathematically $\frac{dH}{dt} = K\,(Q\text{-}Qo)$

$\frac{dH}{dt}$ = heat loss in time dt

Q = T° C of body

Q_o = temperature of enclosure

Q-Q = temperature difference

The relationship between rate of cooling (abcissop) and temperature difference *an ordinate is a linear one* which is not arithmatical proportional. It follows e. g. rate of heat gained by an article which is refrigerated say at 10° C is × 3 times greater at 40° C than it is at 20° C ambient temperature.

2. **Thermocouple, (1) thermo electric current (TEC.) thermo-electric force (EM)**

The Seebeek effect (1826) (2); the Peltier effect (1834) (3); the

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(1) **Thermocouple system**—Copper/Iron, Antimony/Bismuth etc., pointed at both ends.

(2) **Seebeek effect**—if the two functions of the thermocouple are kept at different temperature a current flows around the circuit. Such thermocouple are used to measure temperature of freezers, refrigerators and lyophilizers golvanometrically.

(3) **Peltier**—if a current moves in a thermocouple system the two-functions will be at different temperatures; one junction will be cold and the other hot. The Stronger the EMF the greater the cooling effect upto a maximum beyond which no more cooling is possible.

3. Refrigeration

Principle liquid refrigerant is made to expand suddenly into gas in an air free closed circuit system, because the change of the refrigerant from liquid to gas is isothermal considerable heat energy is withdrawn from the evaporator as a result of which the temperature in the ice box drops. The gas is recirculated into the system to repeat the process again. The temperature being controlled by a thermostat. A refrigerant is a liquid that possesses low isothermal boiling point; the lower the B. P. the greater the cooling effect of the gas phase when it expands e.g., freon, freon 12, arcton, mafron; also strong solution of ammonia in water which is a less effective refrigerant.

4. Refrigerators types

A—*Compressor refrigerator*

Parts–motor, compressor, condenser, evaporator

Advantage–more efficient, ice maker

Disadvantage–short life of compressor

Temperature range–O°C to 10°C

Size–From storage rooms with movable rays on rails to 6 cft capacity for domestic purpose

B—Absorption refrigerator

Parts–boiler, absorber, evaporator, H_2

Advantage–Care free, trouble free–no mechanical parts, economical, runs on kerosene

Disadvantage–less efficient–temperature range 5-10°C, cabinet unit sizes.

5. Deep freezers

For -20°C, single stage electrical compressor is used. Such freezer is used for medium term storage of live viral vaccines for regional centres. For lower temperature as much as -70°C a two stage rotary compressor is required. The first stage brings the temperature down to 35°C and the second stage to -70°. Such low temperature freezers are used for long term storage of live viral vaccines-vaccine in bulk, seedlots in manufacturing laboratories and central supply stores.

Size–rooms for storing large quantities, 9 cft cabinet or chest type.

6. Carbonice

1. Useful for maintaining (-20° to -70°) deep freeze temperatures inside insulated vaccine packings in transit such as when air freighting, or when these are transported over long distance by road.

2. To achieve low temperature freezing (-40°C) and below in laboratory freezers to store seeds; long term storage of vaccine bulk, also more expensive. Because of the latter it is advised to use it in case of emergency such as when power breaks down from mains and no alternative source of power is available; also in the event of power strike. It is less convenient than electricity powered two stage deep freezers.

7. Liquid nitrogen

Because of its low B.P. nitrogen has a cousiderable cooling capacity when it evaporates. The cold is in the gas not the liquid phase the material to be stored is suspended over the liquid phase. Containers

of different capacities are constructed as double walled vessels with vacuum in between. They are available commercially (Cyanamid). Two types of containers are used one for refrigeration (narrow and straws) one of larger capaciry for nitrogen storage. It is useful to manufacturers to keep seeds of live virus vaccine strains.

Methods for producing cold

0. Evaporation*
1. Ice blocks; ice cubes in sealed or tied polythene bags; use of salts.
2. Cold packs—water, brine, alcohol, water mixture contained in a sealed metal container. These can be frozen in the frozen compartments of a refrigerator.
3. Ice making

3.1 The simplest intermittent absorption refrigeration ice maker uses a strong solution of ammonia in water. The cooling system is a two containers apparatus connected through a U-shape tube. As ammonia evaporates it cools down the water contained in a well insulated cold box and turns the water into ice; as much as eight kilos of ice can be produced by this method over a period of 4½ hours. The principle which was used extensively early in the twenties is now being applied at the Rutherford Laboratory, UK with a view to develop a more modern equipment that is more effective.

3.2 Automatic ice maker is commercially available in different capacities to produce and store ice cubes. A convenient size suitable for a district supply station is one with a capacity of 45 kilos for 24 hours.

CHAPTER III

Cold Chain Temperature Control

1. Temperature Recording

The control of the temperature at all stations alone the cold chain is a necessity for two reasons—first in order to secure and maintain the effectiveness of the system and the other in order to *relate situation in the event of vaccine failures.* In Central, Regional and District stations temperature should be recorded thermographically; wherever possible these should be of the multiple points type. Alternatively it could be done by directly reading the scale of the thermometer placed in certain places of the cold room. Reading is done atleast twice a day and when power breaks or reported *six-hourly* and records entered in a temperature ledger. In PHC and sub-centres, a ledger should be kept for recording temperature measured twice a day—morning at 8·00 am – before work starts—afterwards at 2.00 PM after all is over. The temperature of the cabinet and the temperature of the freezer if used for keeping vaccine should be recorded as separate entries in the ledger.

2. Life Expectancy Validity Period=Life Consumed + Residual Life

The quality of the vaccine at the time it is applied/in the field depends on temperature treatment it had as it moved along the chain.

It sometimes happens that a vaccine in the field is inactive though it has been well handled and stored in the peripheral station and the validity is well within the period prescribed by the manufacturer.

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*Wrapping the vaccine in wet gauze; keeping it in an earthenware pot wrapped with wet gauze or coconut coir. Effective for freeze-dried and bacterial vaccine for short time of 1 week at most keeping effectiveness effectiveness depend on low ambient relative humidity and air draught. (see annexure)

How then the vaccine has lost its potency ? The answer lies in the way this particular batch was handled at the different Intermediate stations. We should remember that the actual shelf life of a vaccine is determined by the way it has *been handled* along the cold chain in the different storage stations. If this is the case can we *identify vaccines that have been mishandled ?* This is specially important with respect to very sensitive vaccines like *measles.* Two possibilities–the present practice is to cheek the vaccine from the field. That we do in certain specific situations that warrant such testing but connot be generalized. See annexure 2 about re-testing. Cold protection of the sample of vaccine to be tested presents a problem in the field. Various divices and make shifts are used which are not entirely satisfactory; an important development is the mini refrigeration box which applies Peltier principle and is being developed by the Rutherford Laboratory, U.K.. The other possiblity is to use ,paper indicator on each box of vaccine that will enzyme detect and record temperature and time in the life span of the vaccine. This indicator which is being developed at the National Bacteriological Laboratory in Stockholm has a double feature :

1. A defrost indicator is activated by flash defreezing thus changing the colour of the paper. Useful to detect defreezing of measles vaccine, also that DPT vaccine was frozen.

2. Time indicators which change colour as the life of vaccine is consumed. At a glance the indicator can tell how much more life remains.

CHAPTER IV

Programming the Supply and Storage of vaccine along the cold chain

The plan below was prepared taking into account the following details :

1. Possible dead time for supply e. g. time lapsed between indenting and receipt of consignment.
2. Maximun efficiency at minimum cost
3. The availability of refrigeration facility
4. Minimlze cost of damage in case of break down
5. Validity of vaccine at time it is received in the Central Store

Programming

The Cold Chain		*A Programme for Indenting Supply of Vaccine*		
		Dead time for supply	Recommended size of vaccine stock	Desirable No of consignments per year
Suppliers (overseas)	Suppliers (indigenous)	*One year*	—	—
Central Vaccine Depot		*Three months*	Requirement of 6-months with a validity pariod of 1-year at time it is received	two/three
Regional Vaccine Store		*Three months*	Requirement of 3-month	Four
District H. O.		1. Where good refrigeration facilities exist: *1 month*	3-month	Four
		2. Where refrigeration are not satisfactory; *two weeks*	1-month	Twelve

The cold chain	*A programme for Indenting supply of Vaccine*		
	Dead time for Supply	Recommended size of vaccine stock	Desirable No of consignments per year
Health Centre	Two weeks	1-month	Twelve
Sub-Health Centre	1. When refrigeration is available	1-month	Twelve
	2. When refrigeration is not available, *1 day* on Monday every week to replenish the flasks returned on Saturday	5-days in individual flasks, one for each day Monday to Sturday	Fifty-two
Vaccination Team		The requirement for the same day	260

CHAPTER V

Management of Cold Chain

A. Organization

Workshop (CW) ... Part of Central Workshop or electro mechanical Division

Activities ... Rewinding motors
... Stores

Repair facility (RF) ... One per district; part of an existing hospital workshop

Activities ... Facility for bleeding and recharging refrigerant gas
Facility for soldering and spray painting
Facility for wiring

B. Personnel

Engineer (EN) .. One for the programme

Duties ... Supervision
Programme control
Technical assistance
Ordering parts
Major repairs

Technician (TC) ... Two technicians in a region; one travelling technician and the other fixed with a base at the repair facility; both take alternative duties.

Duties ... Servicing refrigerators
Minor job—on the spot or in a repair facility
Mechanical repair of motor bikes

C. Logistic transport

AIR (A) ... Interstate; viral vaccines–from central airport nearest to destination point. Cable intimation to recipient of AWB and ETA before despatch of consignment

RAIL (R) .. For transportation of FD bacterial vaccine and toxoid other than DPT–also sera

BURA (B)	...	Inter-state; inter-district
CAR (C)		One car per district—part-time service; released by local HS from their pool for transportation with in a radius of 150 miles—for transport of vaccine from airport/railway station to district store and from district store to PHCs.
Motor bike (Mb)	..	One per HC–to link the HC to the district and sub-centres in the area of HC; alternatively use a cycle.
Cycle (Cy)	...	One cycle per vaccination tea for day-to-day transport of vaccine.

D. Containers

- Insulated Refrigerated Packs (IRP)*
- Cold Box (CBX)**
- Vacuum Flask (VFL)***

E. Source of Cold

- Refrigerators
- Absorption type A(ARF)
- Compressor type (CRF)
- Low Temperature Freezers (LTF) –20°C, –70°C
- Absorption Ice Maker (AIM)

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*Two ply corrugated cardboard boxes; foldable at the sides and with flaps at both ends. Measurement is variable from 9 to 27 cft is a practical size. Boxes are lined with a polythene sheet and a 100 mm rigid urethene foam panels on all four sides, top and bottom, For cooling use carbonice blocks if vaccine is to be sent frozen (measles, polio); otherwise use cold packs if the vaccine is to be maintained at 4° to -8oC. When properly packed and *sealed* the box maintains the inside temperature for 5 *days*, It is convenient for freighting vaccines over long distances. These boxes as long as they are in good shape can be recovered and reused.

**Is similar in concept to IRP except that the box is made of either a light metal like aluminium or wood which is less convenient though more effective, Alternatively fibre glass or polyprophylene material may be used and is no doubt the best material for casing. The 75 lit capacity box is a convenient size for transportation of vaccine to district stores. Smaller boxes are useful for the distribution of the vaccine to PHCs from District Stores. For district and PHC stations the number of containers should be double the requirement—one to receive and one to return to feeding station. If unopened and properly sealed, these boxes keep the inside temperature for 7 days.

***These are wide mouth thermos flasks of 3.3 to 4.0 litres volume. The inside is lined with epoxy resin to protect from breakage and the outside is encased in 50 mm thick rigid urethane or polypropylene to protect from shock. The plastic plug can hold an ice block of 1.3 litre and fits into the flask. If unopened the flask keep the inside temperature at 8°C for upto 7 days. It is convenient to transport vaccine from PHC to sub-centre and from sub-centre to the field—in which case a box containing 5-6 fiasks—one flask per day should be supplied to the team by the HC. Two boxes per sub-centre—one for supply and one for return empties.

OPERATION OF COLD CHAIN SYSTEM AT DIFFERENT SUPPLY STATIONS

	Central/State	*Regional District*	*HCs/SCs*	*Village*
A. *Organization*	Wk	Tc	—	
(management and servicing)	En	Tc	Tc	
B. *Logistics*	.....A..... ..... o			
	.....R..... ..... o			
	B... ....B..... o			
Airport	.....C ..... C..... ..... o			
			Mb..... o	
C. *Containers*	.....IRP... .... o			
		CBX .... o		
			VEL..... ..... o	
D. *Source of cold*				
for storage of vaccine	Cold Rooms	CRF	ARF	
	LTF	LTF	AIM..... o	

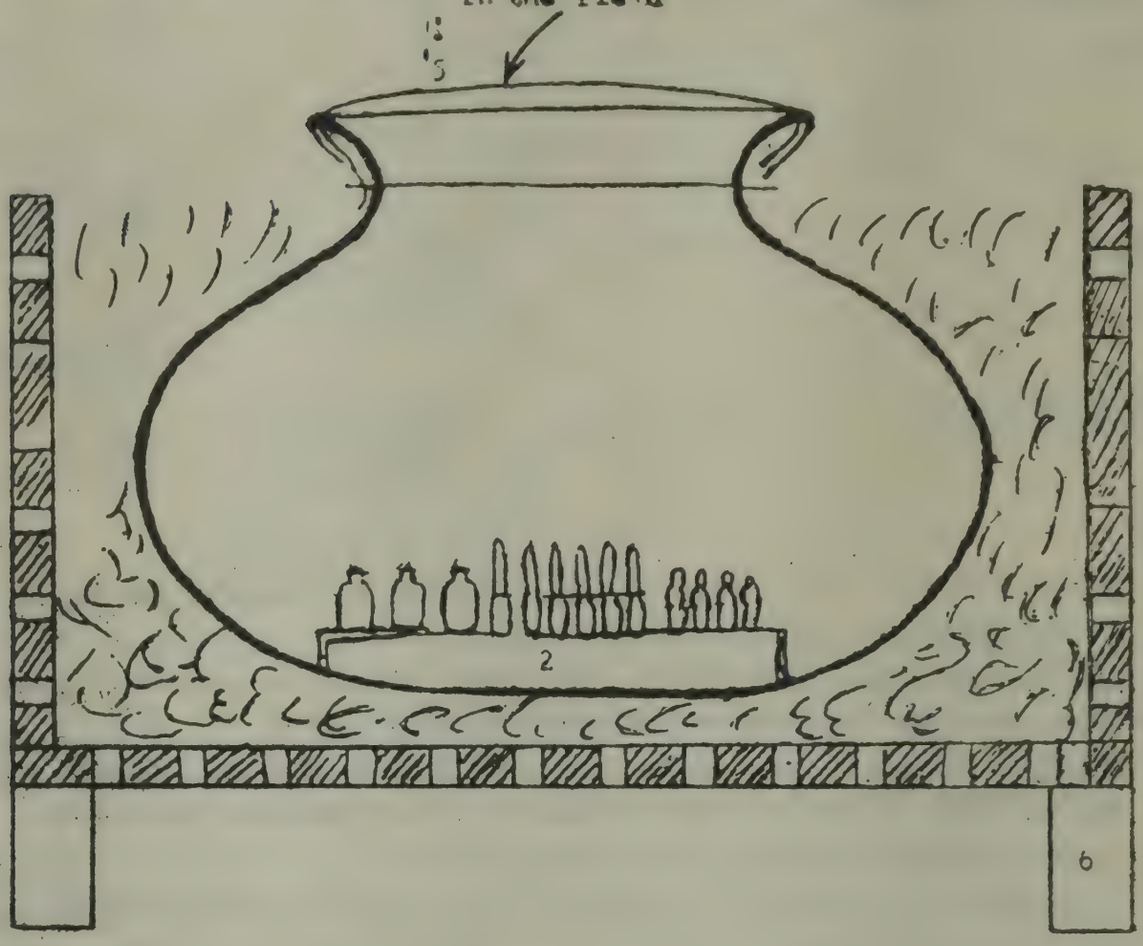
Constraints

1. Operation requires a lot of condition and a free flow of information between the stations and the maintenance service at district/regional.
2. Cost of expandables is high. Cartons, boxes, flasks, need to be continuously replaced. Cost of ice, carbon ice, freight and communication will add to the bill.
3. A PHC should have a source at hand wherefrom they can get ice to top the flasks going to the field and HSC. In most HC ice in the quantity that is needed is just not available.
4. Inadequate budget to purchase and import essential parts.
5. Lack efficiency in prevention and maintenance and swift repairing services at all stations.
6. The refrigerators we use are not fit for topical countries there is a need for the industry to be geared to produce a generation of more efficient refrigerators having a greater cooling capacity better insulated and that could give 10 years trouble free operation. A refrigerator without mechanical moving parts and made of material resisting erosion and which could be operated by fuel other than by power and self defrosting would be no doubt closer to the ideal refrigerators for developing countries.
7. Improper use of refrigerators by the staff in charge and their unconcern with regard to defrositing are important causes for further shortening the life of refrigerators in the HCs.

ANNEXURE I

Vaccines

An earthenware Cooler for short storage of vaccines in the field



1 3 to 5 litres earthenware pot
2 Stand to hold vaccines
3 Coir or vegetable fibres
4 Perforated wooden case
5 Cloth cover or gauze layers
6 Wooden stand

Table 1

Storage times and temperatures for vaccines held at several storage stations

Vaccine	Central[4] Store A	Transport to	Regional or provincial Store[4] B	Transport to	City or District Store C	Transport to	Peripheral Store D	Transport to	Immunization Clinic or Session E
Smallpox[2] (Freeze dried)	Chilled[3] 2°C-8°C 2 years	ambient temperature	Chilled 2°C- 8°C 6 months	Ambient temperature	Chilled 2°C - 8°C 3 months	Ambient temperature	Ambient temperature 1 month	Ambient temperature	Protect vaccine from direct sunlight. When reconstituted use within 1 day. Discard unused reconstituted vaccine.
Measles[2] (Freeze dried) applies also to Mumps, Rubella and yellow fever	Frozen[3] -20 C 2 years	frozen	frogen -20° C 6 months	frozen	Chilled 2°C - 8°C 1 month	Chilled in ice	must be kept cool 2°C - 8°C 1 week	Thermos flask with ice	Protect vaccine from direct sunlight. Reconstitution Fluid must be Chilled. Reconstitute and use within one hour Fill syringe individually for each child. Discard unused vaccine.
Poliomyelitis (oral)	Frozen -20°C 2 years	frozen	frozen -20°C 6 months	frozen	Chilled 2°C - 8°C 1 month	Chilled in ice	cool 2°C - 8°C if possible 1 week	Thermos flask with ice	Protect vaccine from direct sunlight. Use within one working session. Discard unused vaccine.
Poliomyelitis (killed)	Frozen -20°C 2 years	frozen	Chilled 2°C - 8°C 6 months	Chilled in ice	Chilled 2°C - 8°C 3 month	Chilled in ice	cool 2°C - 8°C if possible 1 week	Thermos flask with ice	Protect vaccine from direct sunlight. Use within one working session. Discard unused vaccine.
BCG [2] (Freeze dried)	frogen[3] -20°C 2 years	frozen	Chilled 2°C - 8°C 6 months	Chilled in ice	Chilled 2°C - 8°C 1 month	Chilled in ice	cool 2°C - 8°C if possible 1 week	Thermos flask with ice	Protect vaccine from direct sunlight. Reconstituting fluid must be cool. Use within one working session. Discard unused vaccine.
Diphtheria-Pertusis-Tetanus (absorbed)[1]	Chilled 2°C - 8°C DO NOT FREEZE 2 years	Chilled in ice	Chilled 2°C - 8°C 6 months	Chilled in ice	Chilled 2°C - 8°C 1 month	Chilled in ice	cool 2°C - 8°C if possible 1 weak	Thermos flask with ice	Protect from direct sunlight. Use within one working session. Discard unused vaccine.
Quadruppl Diphtheria-Pertussis-Tetanus-Polio (killed)	Chilled 2 C - 8°C DO NOT FREEZE 2 years	Chilled in ice	Chilled 2°C - 8°C 6 months	Chilled in ice	Chilled 2°C - 8°C 1 month	Chilled in ice	cool 2°C - 8°C if possible 1 week	Thermos flask with ice	Protect from direct sunlight. Use within one working session. Discard unused vaccine.

1 These vaccines may or may not contain a mineral carrier (aluminium hydroxide or phosphate) as an adjurent.

2 All freeze dried vaccines must be reconstituted before use with the reconstituting fluide supplied by the manufacturer for this purpose. This must be cooled before use for reconstitution.

3 The reconstituting fluid for these vaccines must not be frozen but kept chilled at 2°C - 8°C.

4 Please see remarks concerning times in text on page ?

STORAGE TIMES AND TEMPERATURES FOR VACCINES HELD AT SEVERAL STORAGE STATIONS

TABLE 1 (Continued)

Vaccine	Central Store + + A	Transport to	Regional or Provincial Store B	Transport to	City or District Store C	Transport to	Peripheral Store D	Transport to	Immunization Clinic or Session E
Diphtheria Tetanus Toxoid (Absorbed*	Chilled 2°C - 8°C do not freeze 3 years	Chilled in ice ——→	Chilled 2°C - 8°C 1 year	Chilled in ice ——→	Chilled 2°C - 8°C 6 months	Chilled in ice ——→	Coolest part of building 1 month	Thermos flask with ice ——→	Protect from direct sunlight. Use within one working session. Discard unused vaccine.
Tetanus Toxoid (Absorbed*	Chilled 2°C - 8°C do not freeze 3 years	Chilled in ice ——→	Chilled 2°C - 8°C 1 year	Chilled in ice ——→	Chilled 2°C - 8°C 6 months	Chilled in ice ——→	Coolest part of building 1 month	Thermos flask with ice ——→	Project from direct sunlight. Use within one working session. Discard unused vaccine.
C lera or Typhoid or tab	Chilled 2°C - 8°C do not freeze 2 years	Chilled in ice ——→	Chilled 2°C - 8°C 6 months	Chilled in ice ——→	Chilled 2°C - 8°C 1 month	Chilled in ice ——→	Cool 2°C - 8°C ⩾ 1 week	Thermos flask with ice ——→	Protect from direct sunlight. Use within one working session. Discard unused vaccine.

*These vaccines may or not contain a minerol carrier (aluminium hydroxide or phosphate) as an adjuvant.

*Please see remarks concerning times in text on page 7.

TABLE 2

THE RE-TESTING OF VACCINES

Vaccine	No. of doses involved justifying test	No. of doses* needed for test	Conditions of air transport	Type of test for potency	Duration of test (minimum)	Time when answer expected (allowing for repoated test)
Samallpox (Freeze dried)	Vaccine in plentiful supply 10 000	200	ambient temperature	Virus titration	7 days	2 weeks
Measles (Freeze dried)applies also to Mumps, Rubella	1 000	50	chilled 2°C-8°C "cold dogs"	Virus titration	10 days	3 weeks
Poliomye-litis (oral) applies also to yellow fever	1 000	50	ftozen -20°C (solid carbon dioxide)	Virus titration	7 days	3 weeks
Pollomye-litis (killed)	5 000	50	chilled 2°C - 8°C "cold dogs"	tests in animals	4 weeks	3 months
BCG (Freeze dried)	1 000	25	chilled 2°C - 8°C "cold dogs"	live bacterial titration	3 weeks	months
Diphtheria-Pertussis-Tetanus	5 000	100	chilled 2°C - 8°C "cold dogs"	tests in animals	4 weeks	2 months
Quadrupple Diphtheria-Pertussis-Tetanus-Polio (killed)	10 000	100	chilled 2°C - 8°C "coid dogs"	tests in animals	4 weeks	3 months
Diphtheria-Tetnus Toxoid	5 000	100	chilled 2°C - 8°C "cold dogs"	tests in animals	3 weeks	2 months
Tetanus Toxoid	5 000	100	chilled 2°C - 8°C "cold dogs"	tests in animals	3 weeks	2 months
Cholers or Typhoid or TAB	5 000	100	chilled 2°C - 8°C "cold dogs"	tests in animals	3 weeks	2 months

*Taken from at least five different containers

DRAFT

Constructing Cold Boxes for the Transport of Vaccines*

—Expanped Programme on Immunization
12 October, 1977

Contaienrs are urgently needed to transport vaccines at temperatures just above freezihg in outside temperatures between 30°C. These containers are of two types: the first type is a "cold box" for supplying vaccines stores by vehicle or for mass vaccination in the field using a vehicle. The second type is a carrier for taking smaller amounts of vaccine by hahd, or on a bicycle or motorcycle to vaccination sessions in the field.

This paper is a guide only to the design and construction of cold boxes suitable for loading on to a vehicle and transporting vaccine from store to store, or supplying a mobile vaccinating team. A further review is in preparation of various types of vaccine carriers available on the market and a guide to the adaptation of certain types to improve their "cold life" performance.

Recently, cold boxes made by the National Bacteriological Laboratories in Stockholm (see annex 1) specially for the Expanded Programme on Immunization in Ghana, have been tested in the field. They are robust and have a cold life in field temperatures of one week. Boxes of this type are not difficult to cohstruct locally ahd the quantities required are well within the capabilities of a small industry willing to supply the national immunizing agency.

There are five steps in designing and producing a cold box :

—choosing the size of the box
—deciding on materials and construction
—Choosing fittings and finishes
—testing the performance
costing the cold box and commissioning the prototype.

Choosing the size of box :

Calculations for estimating the required capacity of the cold box, and for prodicing the 'cold life' of the box appear in annex 2. This paper describes the design of two cold boxes with the following specifications :

Box Type	Vaccine Capacity Litres	Insulation Thickness/ Type	Ice pack Capacity/ Thickness	Dimensions External/[2] Internal/[1] Nett internal CMS	Closed		Open 10×30 secs each days[3]	
					Days life at 30°C	Days life at 40°C	Days life at 30°C	Days life at 40°C
A	30	100 mm rigid urethane foam	14 litres 2.5 cms	56×56×56 36×36×36 31×31×31	14	10	5	3·5
B	70	100 mm rigid urethane foam	26 litres 2.5 cms	66·4×66.4×66.4 46.4×46.4×46.4 41.4×41.4×41.4	16	12	5	3.6

[1] A container surrounded by thermal insulation and jined with ice packs which control the temperature of the vaccine at just above freezing temperatures.

Excluding casting material

[3] Equivalent roughly to 500/A and 1000/Bg ms water inserted at ambient temperature.

The number of doses of measles, polio, BCG, smallpox or DPT vaccines which can be carried in each box varies greatly with packaging, but a rough guide is that Box-A will carry some 2000 doses of any of these vaccines (including diluent), and Box-B will carry about 1000 doses of these vaccines. The diluent for freezedried vaccine is assumed to be in the cold box with the vaccine.

The cold box is assumed to be a cube in shape because the surface area is minimized this way. The surface area partly determines the 'cold life' of the box; the smaller the surface area, the less heat is gained and the longer the life of the ice packs.

The insulation chosen has the highest perfomance and is usually the most expensive at arrouud US$ 100 per cubic metre. The insulation cost for Box-A would therefore be US$ 13 and the insulation for Box-B US$ 20.

The smaller the box, the more space and weight is relatively used for insulation, the more bulky to carry in a vehicle. Box A is 78 cm^3 per dose of vaccine and Box B is 56 cm^3 per dose of vaccine. So the box should be sized carefully for the amount of vaccine to be carried.

The larger the box chosen, the heavier. The table below gives approximate weight in kg of the cold box and its components :

	Ice packs	Wooden casting	Vaccine	Insulation	Fittings	Total
Box A	14	22.5	3	4.5	1	45.0
Box B	26	31.7	7	6.8	1	72.5

Deciding on materials and construction :

The following elements need to be considered :

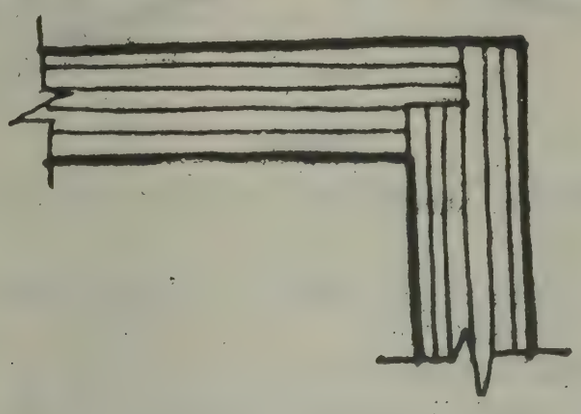
—external casing

—internal lining

—insulation

External casing :—This should be a locally available strong material which is either wood or galvanized steel sheet.

Plywood 15-22 mm thick is suitable if it is treated to resist local climatic conditions. Sea air and high humidity requires marine-type plywood. Pressure impregnation is required for insect (such as white ant) proofing in many countries. Corner jointing should be strong. A suitable joint for plywood is shown in figure 1. This should be glued with a casein or epoxy glue and pinned.



Softwood is not suitable because of its softness and inability to resist water and insects.

If hardwood is used, boards should be tongued and grooved and assembled with glue and pinned.

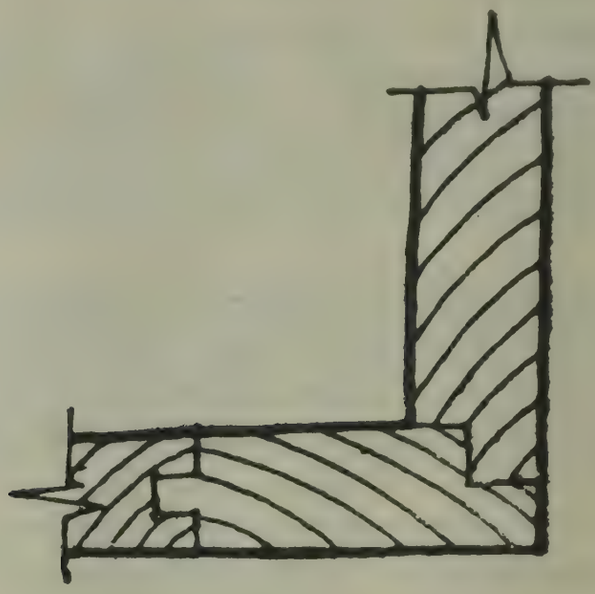


Figure 2

Corner joints should be either :

Dovetail joint :

Comb joint :

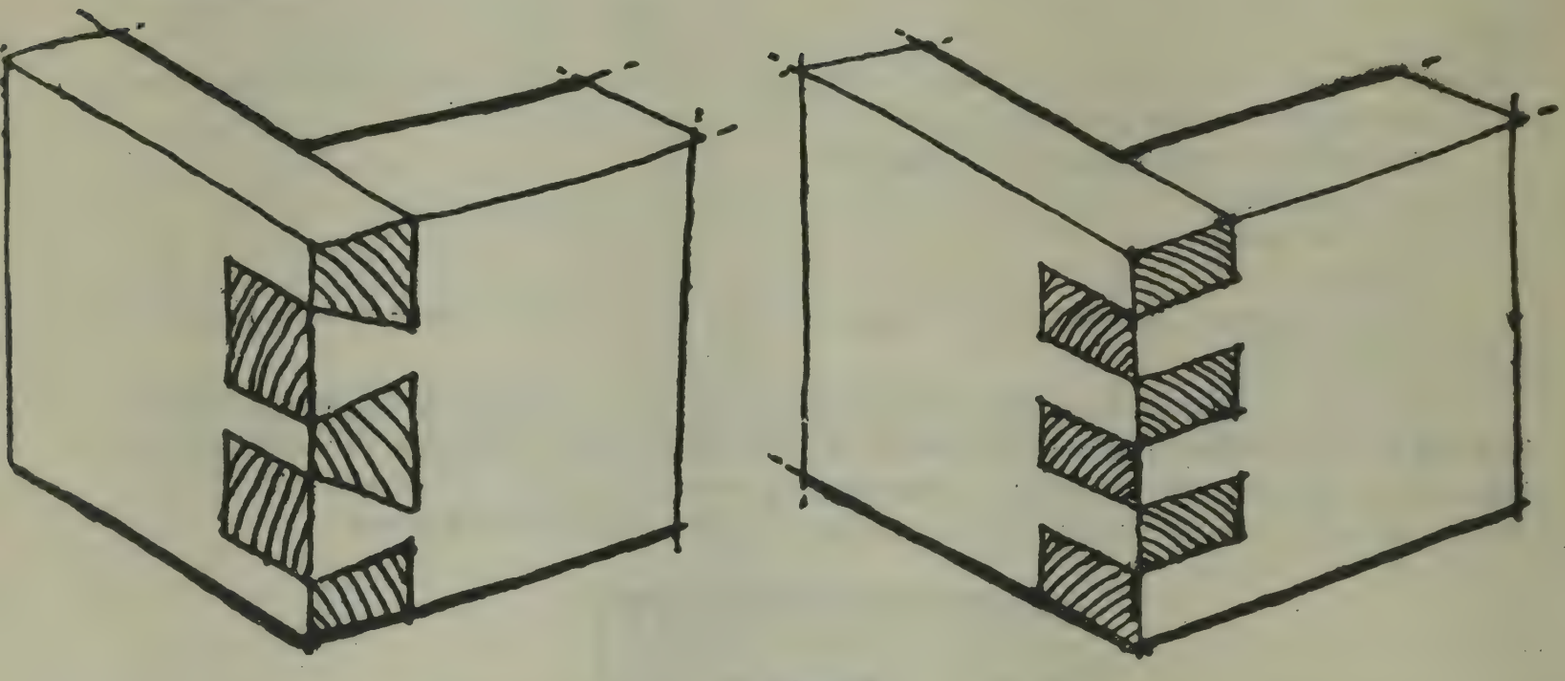


Figure 3

Internal corner reinforcement should not be used as this reduces the effectiveness of the insulation.

If rigid urethane foam is chosen as an insulation it bonds strongly to the wooden casing of the box so that a thinner casing can be used (15 mm) in most applications.

Galvanized steel sheet is also a suitable material. Corners may be folded and riveted or bolted. Welding is not suitable because it removes the galvanizing and exposes the steel to rusting. The gauge should be chosen according to local availability and estimates of weight and strength.

The inner lining protects the inside of the insulation in the box and under the lid. The lining of the box is this general shape :

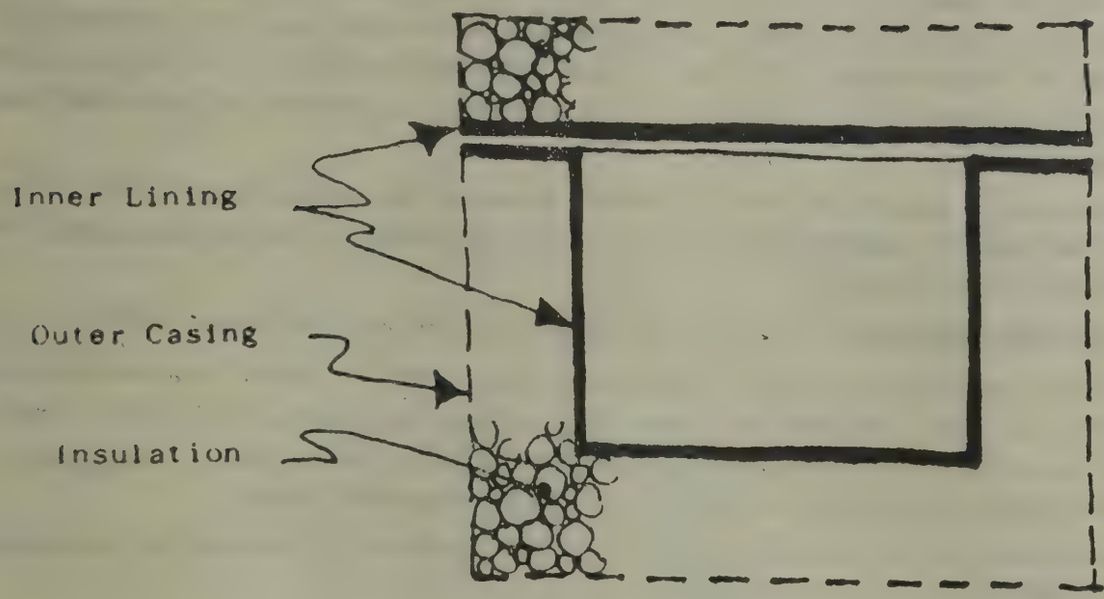


Figure 4

For inner lining the following materials can be used :

—plastic, with welded or glued joints

—aluminium or 3 mm waterproof plywood

It is important for the lining to be waterproof unless rigid urethane foam is used as an insulation. Water condensed from the icepacks will soak through into the insulation otherwise, and make it ineffective. Joints and fixings should not protrude into the insulation space since this reduces its effectiveness. The inner lining should only be secured to the outer casing by the edge, or lip of the lining. *No* other supports to the lining should connect it with the casing as this reduces the effectiveness of the insulation.

Insulation—All types of insulations absorb water to some extent and as the moisture level rises the insulation becomes less effective. Rigid urethane foam absorbs the least water while plant fibres (likely to be locally available) absorb the most. So if local materials are used it is most important to completely seal the insulation cavity. The principal of most insulation material is to achieve the lowest density of material possible while completely isolating small pockets of still air. Natural insulating materials such as :

cork chips	sponge
capoc	straw
wool waste	saw dust

Should therefore not be packed too tightly as this reduces insulating efficiency. Certain gases have a better insulation than air which is why rigid urethane foam is such a good insulator.

Foam polystyrene can be manufactured with Freon gas instead of air bubbles. This nearly doubles its efficiency as in insulator.

Foam polystyrene is usually available in sheet form and should be cut 'oversize' and forced into the casing of the box to provide a good seal between adjacent sheets of insulation.

Rigid urethane foam is available in sheet form or as chemicals. These are straight forward to use without special equipment. A measured amount of component 'Ā' liquid is poured directly into the cold box with a measured amount of component 'B' (see Annex 3) and the inner lining secured down *immediately*. The chemicals foam up, filling the whole cavity and then become rigid in about 90 seconds. Box A requires about 2·28 litres of each component and Box B, 4·76 litres (including the lid). If a hardwood casing is used, adhesion to this insulation is improved by leaving the inner surface of the box unprepared.

It is important to measure the chemicals exactly to match the volume in the wall of the box. Too much chemical will raise the density of the insulation and lower the insulation performance. Too little chemical will fail to fill the volume.

Choosing fittings and finishes : Remember, fittings must be installed ***before*** insulation is poured.

Steel finishes should be galvanized. The outer surface of the box should be as reflective as possible White paint or alluminium oxide paint will reduce the surface temperature of the box. Unfortunately, pressure impregnation of plywood and galvanizing on steel reject or 'show through' many paints. Locally available points should be tested first on scrap before full painting work begins.

A clear warning label should be stencilled on to the top surface of the cold box. An example under consideration with IATA is shown in figure 5.

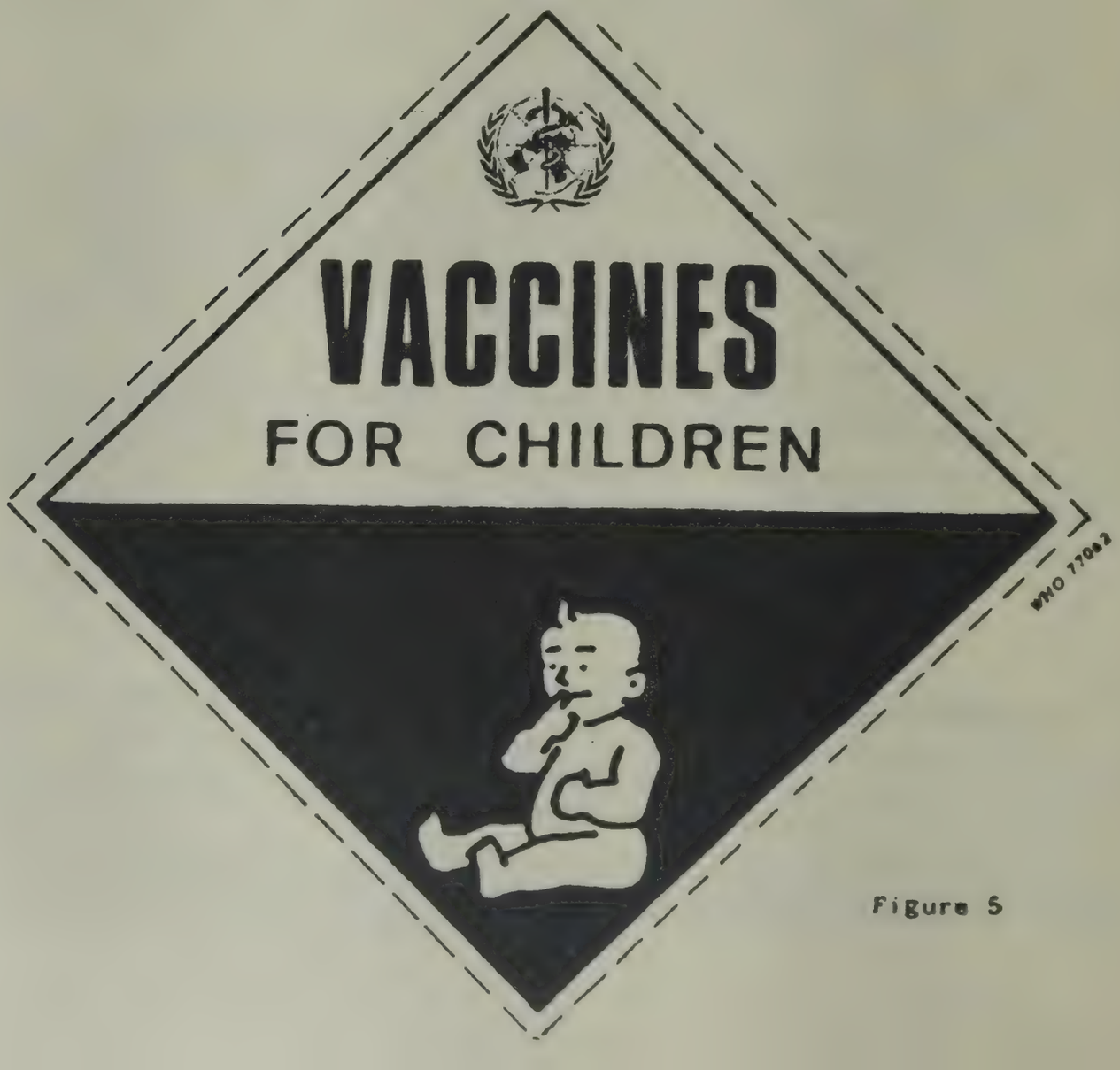


Figure 5

Fittings to be selected are as follows :

— dial thermometer
— hinges
— seal
— catches and locks
— handles
— corners and stays
— cold packs

A dial thermometer—should be fixed to the front side.* A hole should be drilled to enable the sensor tube to be inserted into the cold box. It ts most important to seal the tube to the casing and the lining using a soft 'mastic', or sealing compound. The face of the dial can then be fixed to the casing using self-tapping screws : See figure 6.

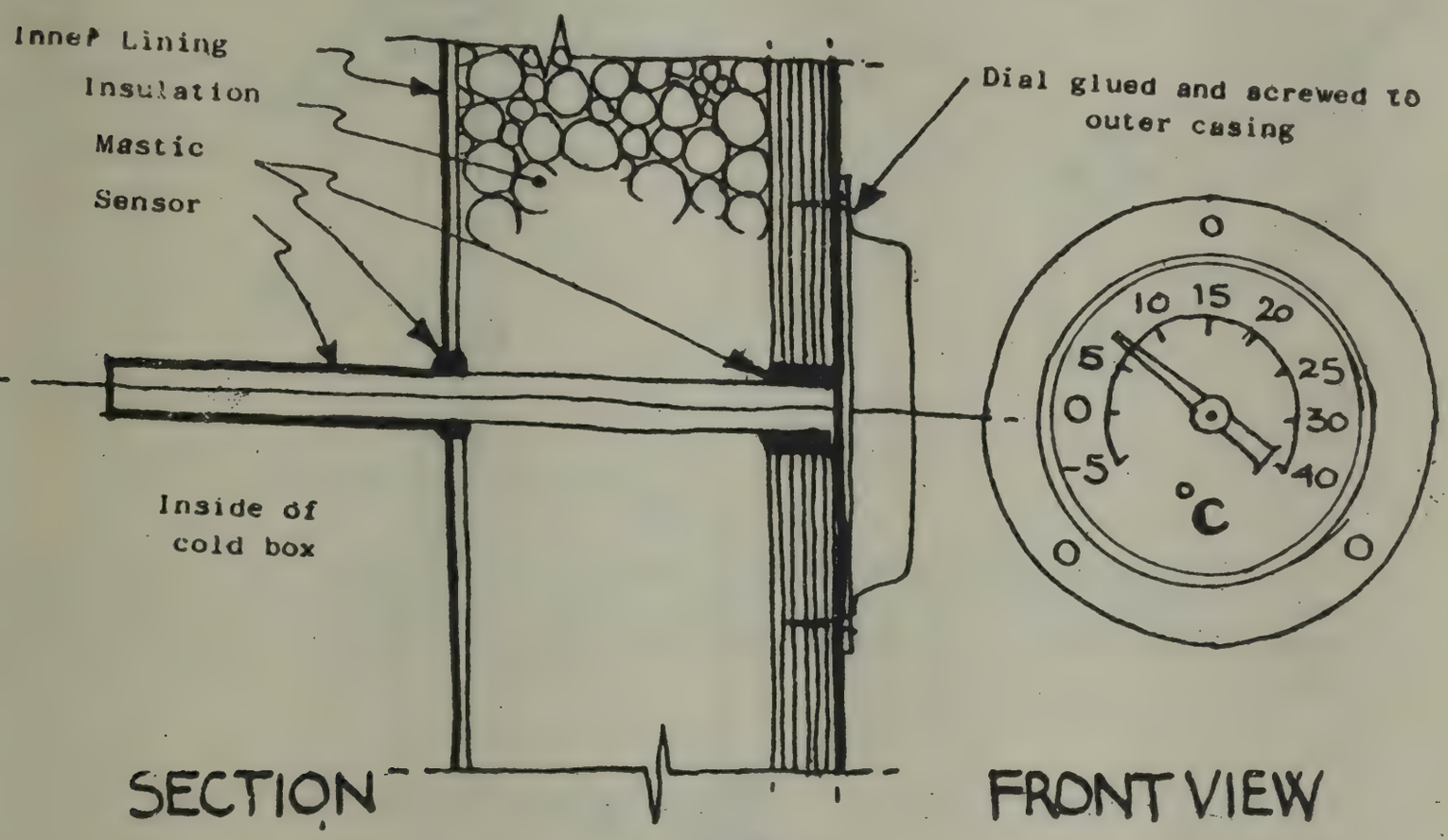


Figure 6

Hinges—should be strongly fixed to the casing. This can be achieved using a 'piano hinge' (see figure 7 A) and many screw fixings or a 'strap hinge' (see figure 7 B) bolted to the casing.

*A suitable specification is as follows :

PAT No. SLB 252 : 2½" (64 mm) Bi-metal Actuated Dial Thermometers. Range −40/+60°C. Pressed steel case with combined bezel and flushmounting flange finished stove enamel hammer grey. Flange drilled for 3× hole fixing. Perspex 'window'. Centre back entry gradc 18.8 stainless steel stem 5/16" (8 mm) diameter, length 200 mm (7⅞") overall. Dial marked with coloured zone between +2° and +8°C. (Exact colour to be determined). Accuracy ±1%. Full scale value.

Quantities :	Singles	Lots 10×	Lots 50×	Lots 100×	Lots 250×	Lots 500×	Lots 1000
Costs in US$:	10.8	9.54	9.11	8.28	8.06	7.87	7.65

G. H Zeal Limited, Lombard Road Merton, London SW 19 3 UU.

Telephone : O1-542 2283/6 O1-542 7216/7.
Telegrams and Cables : Zealdom London—Telex 929519.

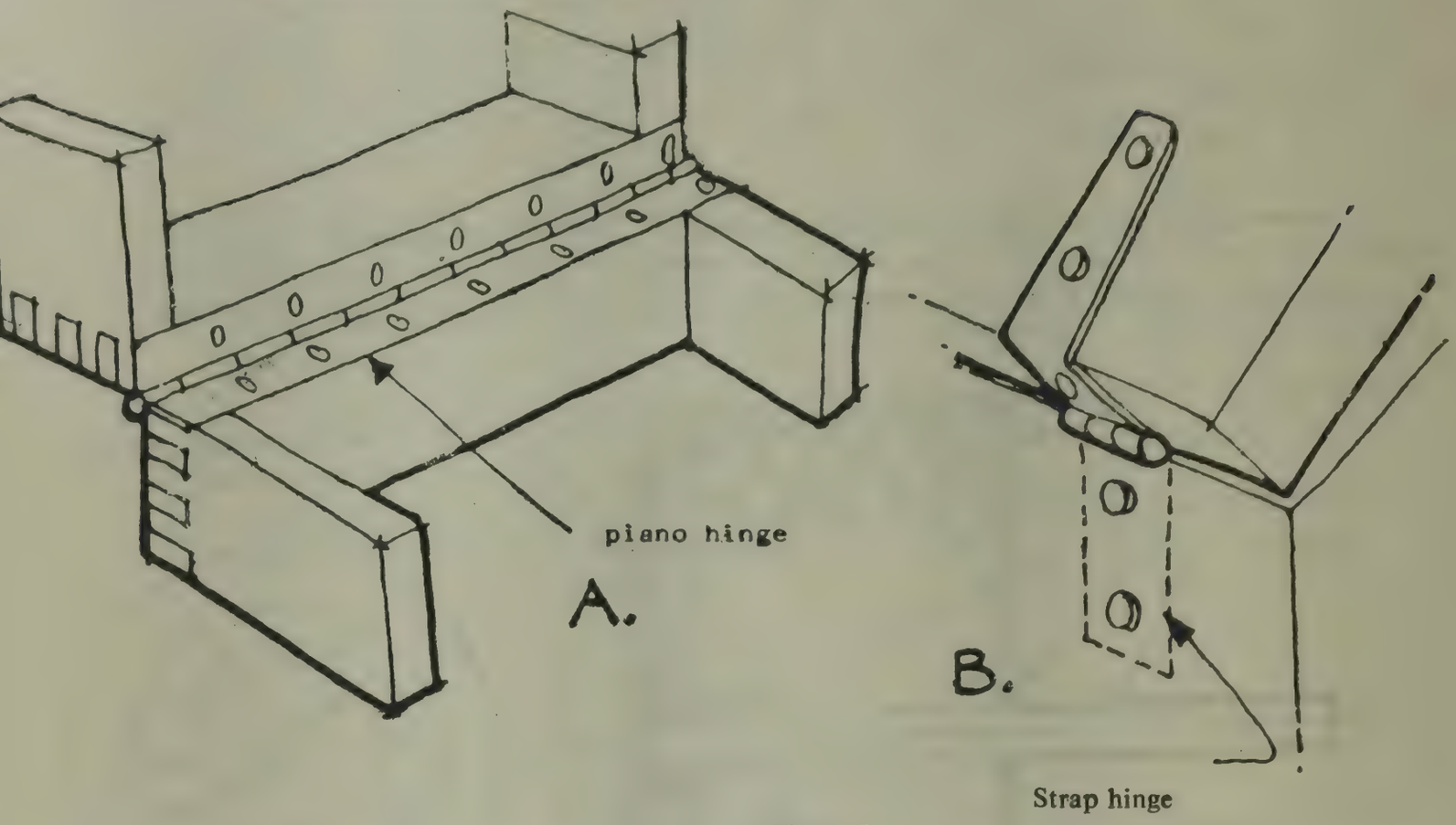


Figure 7

A seal—is required so that when the lid is closed the box remains airtight. This should be a neoprene or pvc plastic material, not rubber. Rubber perishes quickly in tropical climates. The seal should be glued and pinned either to the lining of the lid or to the box; (see figure 8) using an epoxy based glue.

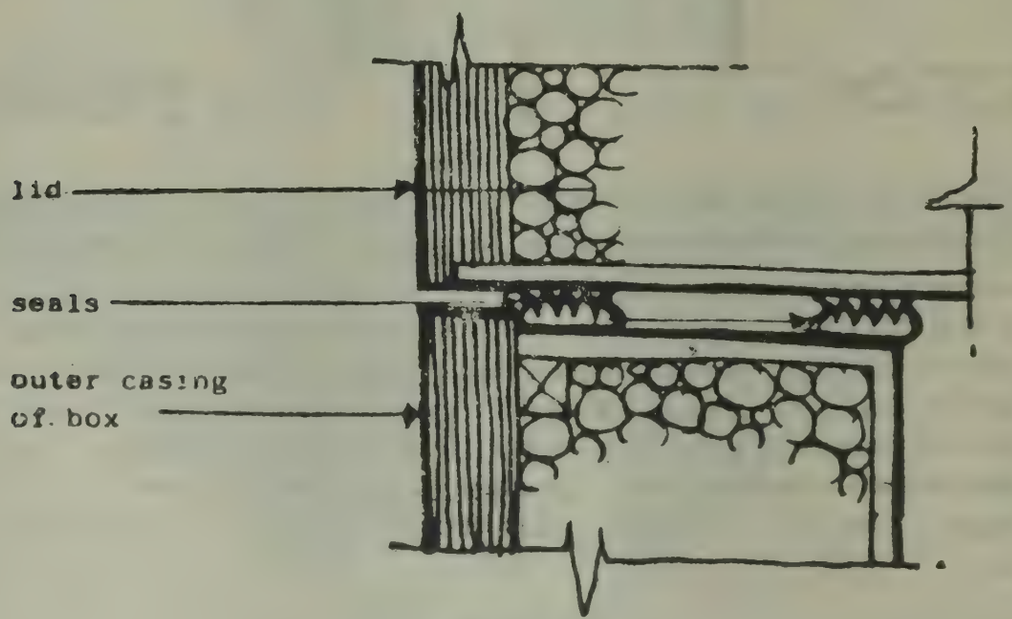


Figure 8

Catches—should be fitted, two per box. These should provide pressure on the lid to compress the seal when closed. The adjustable types are preferable (see figure 9)

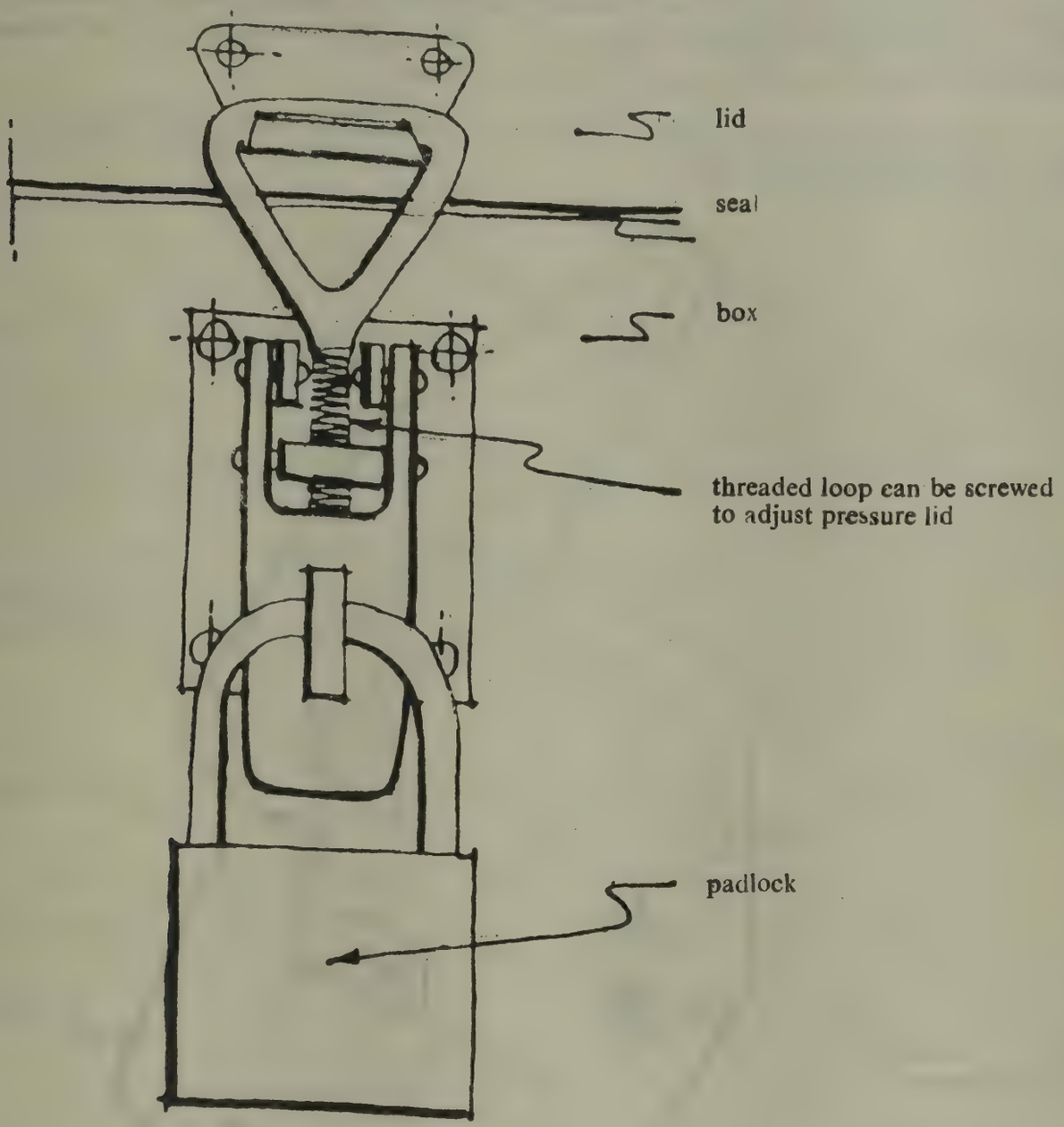


Figure 9

Each catch should be designed so that a padlock can be fitted. Padlocks are more reliable than other locking systems and they are easier to replace if the key is lost. Catches should be fixed with coach bolts and nuts, not screwed to the box.

Handles—Heavy duty 100 mm or 150 mm cabin handles should be fitted at each side of the box so that it can be lifted. (see figure 10)

Corners and stays—Metal corner reinforcements should be fitted. These should be;

— robust
— screw fixings long enough

Chain stays can be fitted at the sides of the box using heavy duty chain secured with a bolt at each end.

Ice packs—are plastic bottles filled with water which can be frozen and arranged around the sides of the box, across the base and over the top of the vaccine under the lid. As long as some ice remains frozen the cold box will remain at near freezing temperatures. The bottle should be about 25 mm thick and a convenient width and height to fit into the box meaning that several bottles will be required. The bottles should be filled to within 5 mm of the top with water.

The plastic of the bottle should be polythene, because the more brittle material tend to crack during handling when they are frozen.

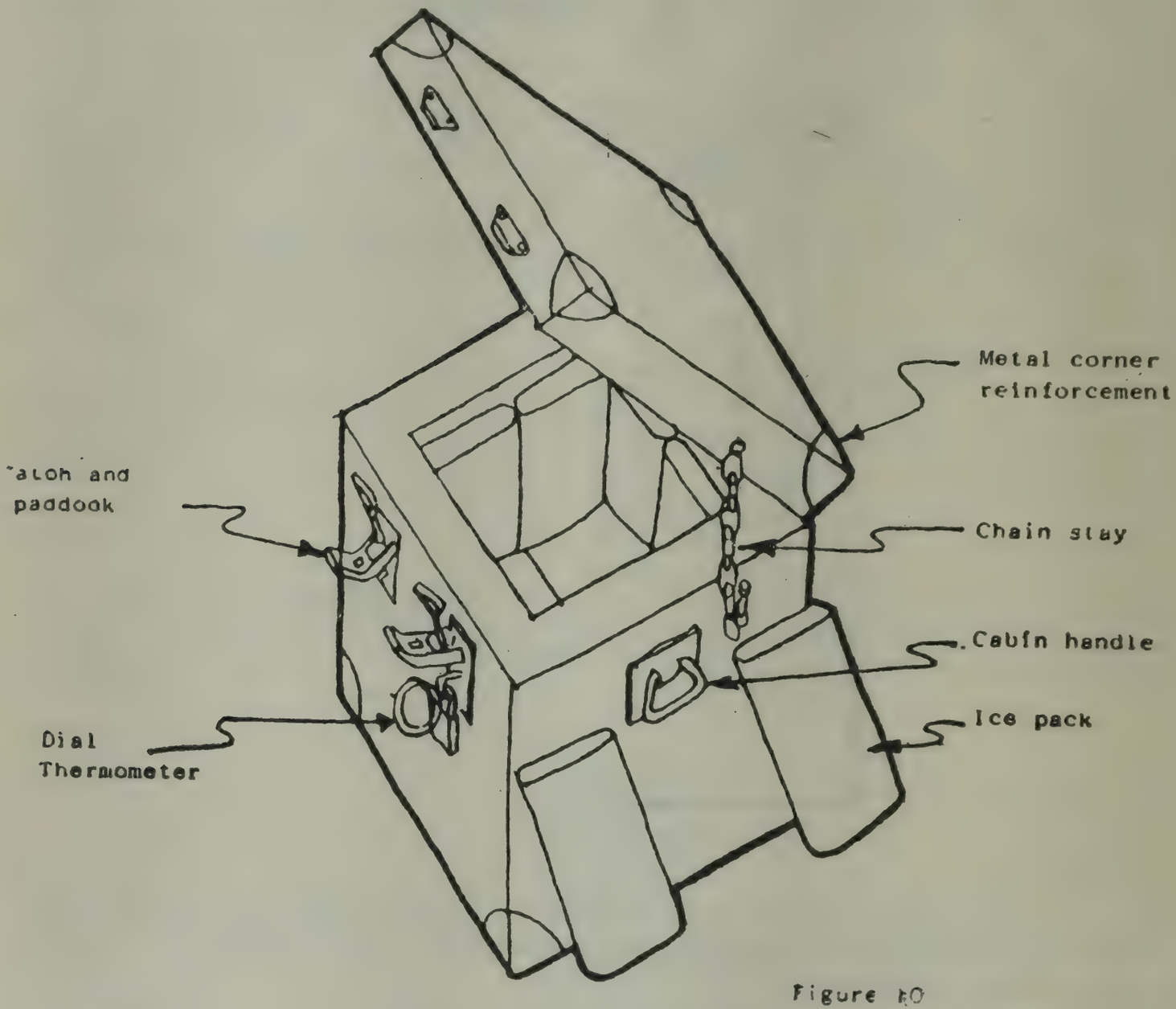


Figure 10

Prototype Testing

When the design specification for the cold box has been decided, a manufacturer can be commissioned to build a single prototype and carry out performance tests. The cost of this prototype will naturally be higher than the final production version manufactured in some quantity. But it should be possible to obtain from the manufacturer an approximate price, given an estimated quantity which will be required.

The testing of prototypes should be as follows :

Test 1 :—Each box should be loaded with its full complement of ice packs frozen to -20°c. Cardboard boxes should be loaded in place of vaccine and the lid of the box closed firmly. The temperature should then be read each 15 minutes until it reaches 0°C after which it should be read once every 3 hours during the day until the temperature reaches +20°C. The ambient temperature should be controlled at +40°C.

Test 2 :—Test 1 should then be repeated for +30°C ambient.

Test 3 and 4 :—Test 1 and 2 should then be repeated opening the box 10 times per day for 30 seconds each time. The intervals between openings are not important but they should be kept constant from test to test.

Costing The Cold Box And Commissioning The Prototype

Once the testings on the prototype is complete and proved to be satisfactory a firm estimate of cost should be obtained from the manufacturer for a quantity of cold boxes. The cost per box for different quantities of cold boxes will vary according to the economies of buying materials in bulk and organizing the production line The manufacturer will be able to discuss the most economical quantities of box to be manufactured in one batch. The manufacturer must set up quality control of finished boxes. This should include periodic performance testing of a sample of boxes.

When the first batch of boxes have been distributed and are in use it is worth making an early evaluation of the boxes in the field. Any changes which need to be made to the design can then be incorporated for further batches of boxes manufactured.

ANNEXURE I

Cold Boxes from the National Bacteriological Laboratory, Stockholm, on trial in Ghana Programme

Material Used

Outside—Plywood specially treated to withstand water-boiled water resistant i. e. if boiled in water 2-3 hours the wood withstands the treatment. The plywood is the same used in building small boats.

Inside—The insulation used is 100 mm thick Poly-urethane (market name in Sweden "Bonocell", a cellulose derivative) Because the Poly-urethane is brittle a thin layer of plastic 2/3 mm of P. V. C. plastic is used as an internal lining.

Size (*a*) The large Box is 700 × 550 × 500 mm (outside measurements)

(*b*) The small Box is 550 × 500 × 470 mm

Weight—Large Box—empty : 24.7 kg; fully loaded 46 kg.

Small Box—empty : 18 kg; fully loaded 30 kg.

Cooling medium—Cooling is done by cooling packs (cold dogs) containing water with an additive to increase viscosity. Each cold pack measures 195 × 120 × 38 mm and swells during freezing-the 38 mm ean swell up to 50 mm.

The big box takes 22 cold packs. The small box needs 14 cold packs. They take up 26 litres and 16 litres respectively of the inside space.

Loading capacity—The big box can take about 3000 doses (288 × 10 ml vials) and the small box about 1500 doses (150 × 10 ml vials)

Temperature chart (*a*)—using cold packs at -20°C(see chart) for the first 2 days the box temperature keeps below freezing point. (Vaccines that should not be frozen like DPT should not be kept with-20°C packs). The box keeps from the third day a temperature of 0°C until twelfth day, (Ambient temperature: + 24°C;

(*b*) using cold packs ± 0°C and maximum melting ice within, the temperature of ± 0°C is kept for 5 days at an ambient temperature of +34°C (even with 6 openings two minutes each day of the box)

Reconstituting fluids—These should be kept cool but never in boxes below ± 0°C as the sealed glass cracks on being frozen.

Note—The cold boxes are on trial in Ghana. There are likely to be improvements in the light of experience.

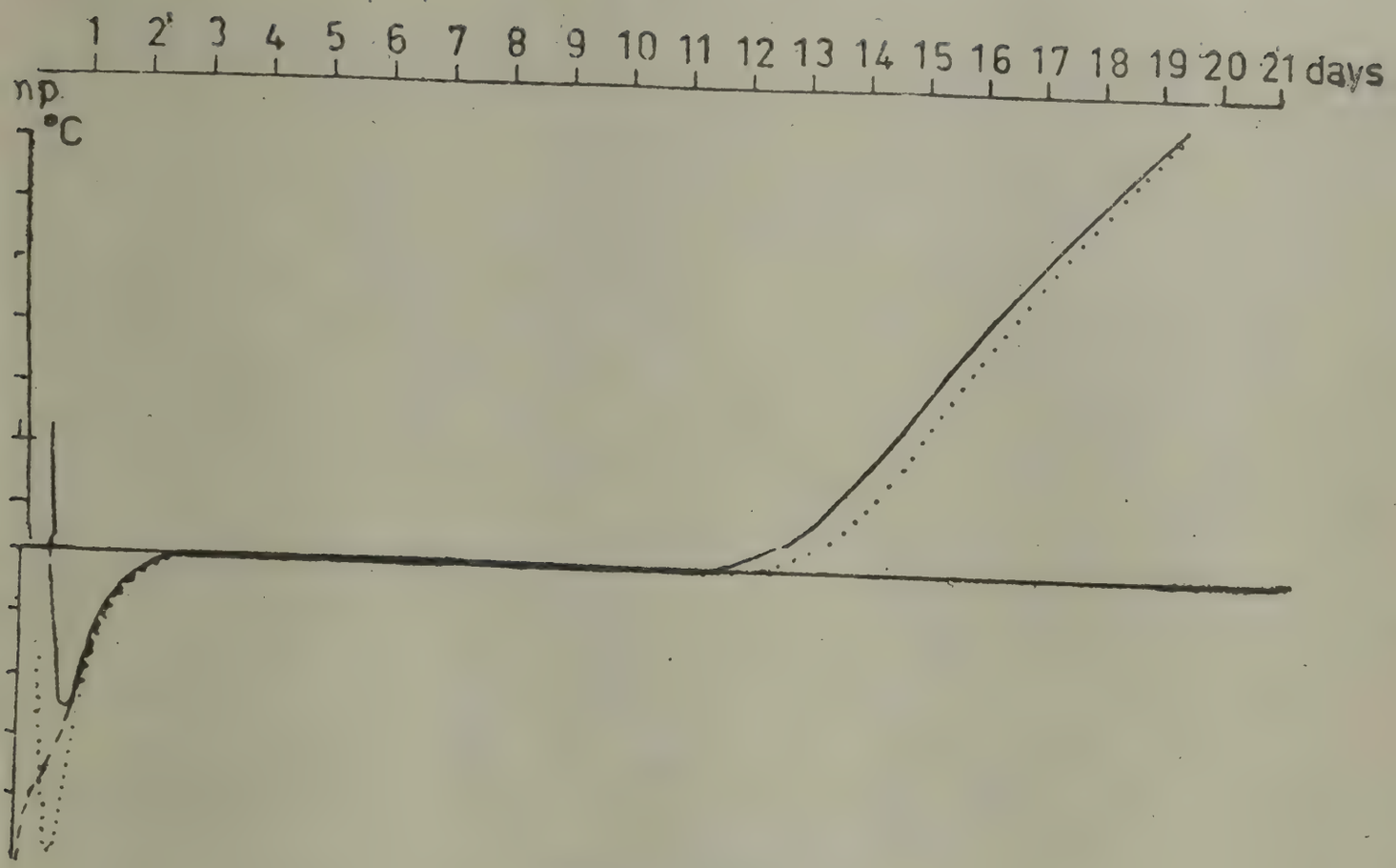


Fig. 1

———Center.

———Space between vials and cold dogs.

———Space between cold dogs and inner wall of the box.

Box A and B

Ambient temp. +24°C

Cold " C, no opening of the box

m 5F

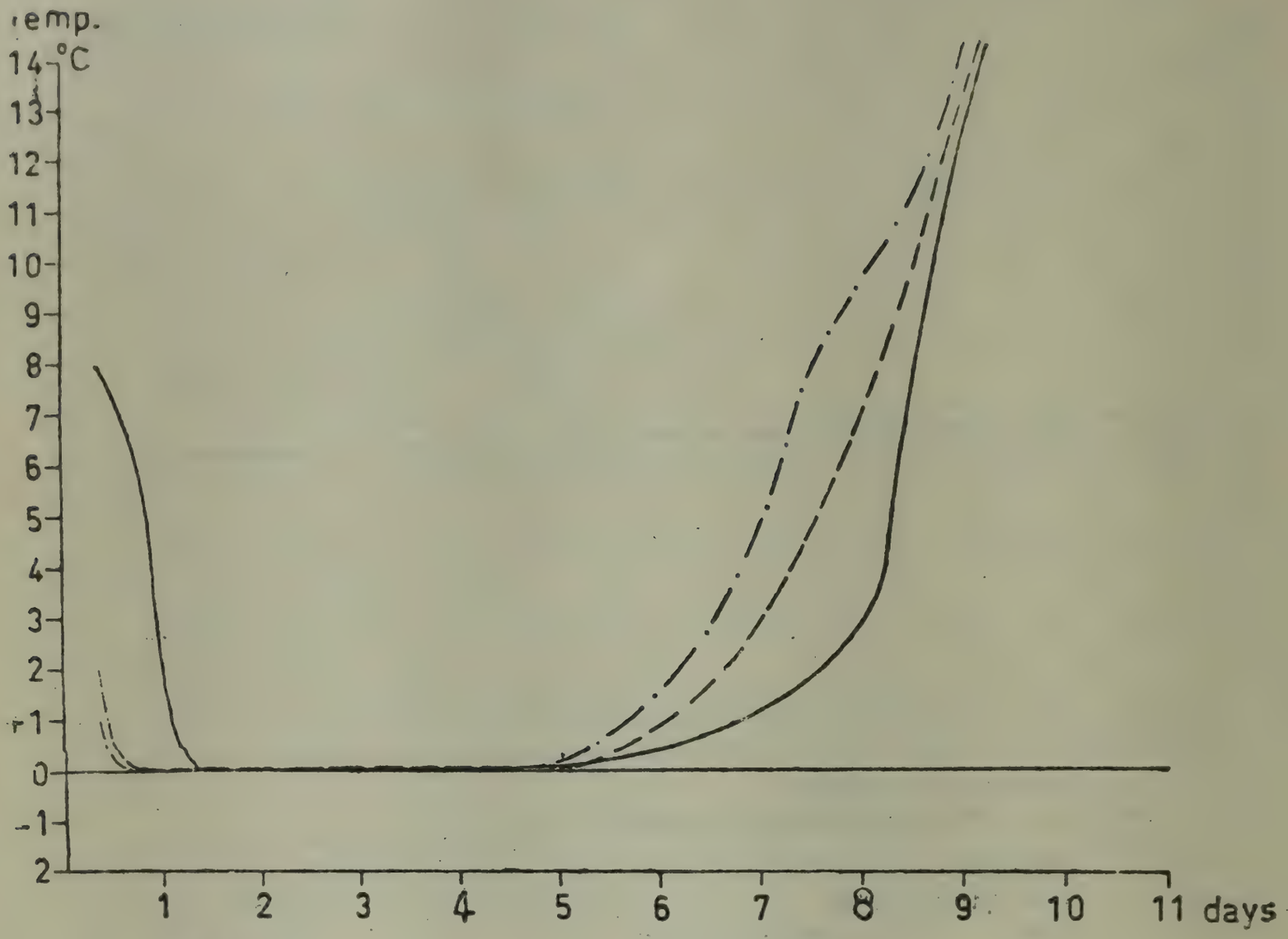


Fig. 2

———Center

———Space between vials and cold dogs

———Space between cold dogs and inner wall of the box

Box A and B

Ambient temp. +34°C

Cold dogs ±0°C

Opening of the box and removal of 12 vials (10 ml) 6 times a day

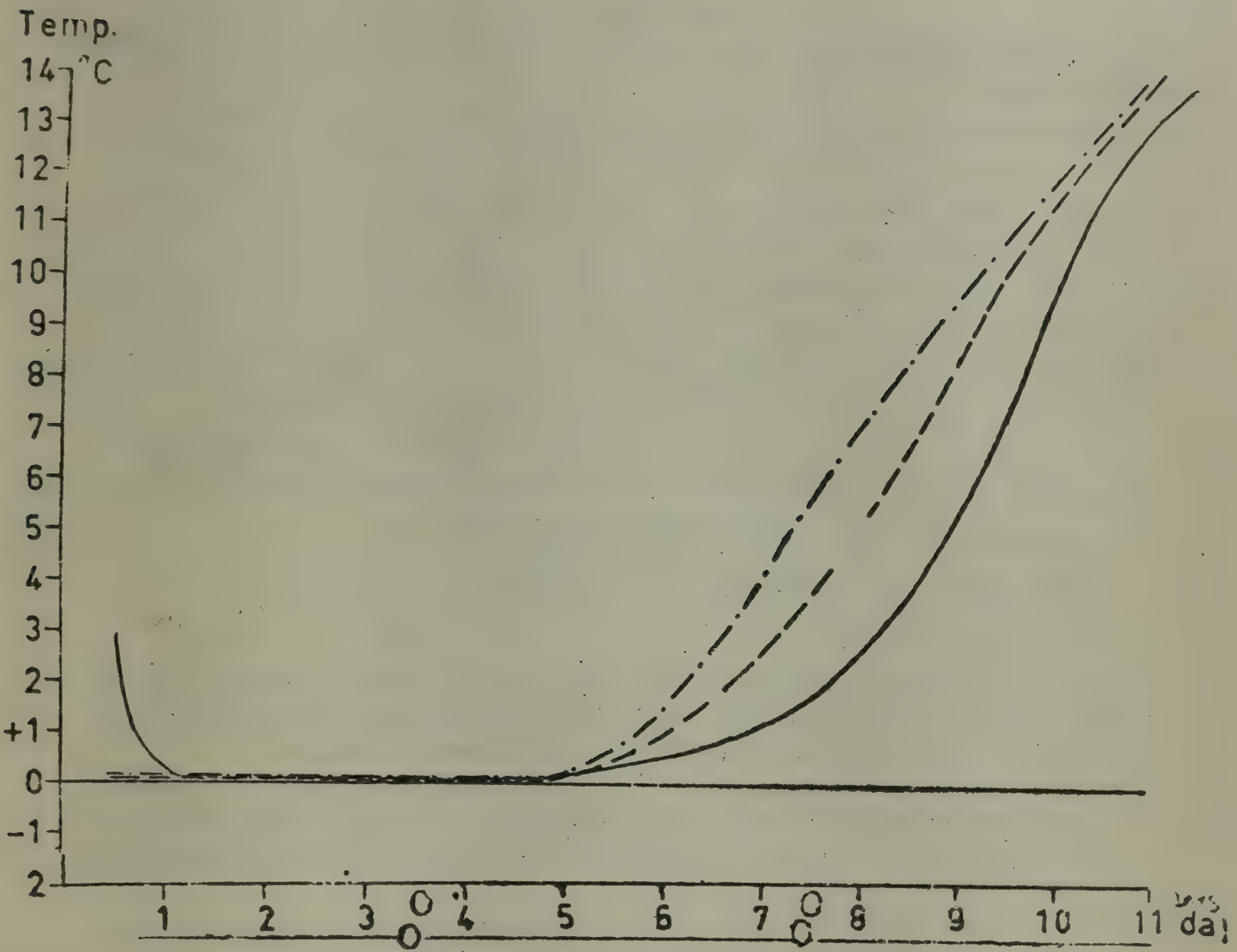


Fig. 3

Center

Space between vials and cold dogs

Space between cold dogs and inner wall of the box

Box A and B
Ambient temp. +34°C
Cold dogs ±0°C
No opening of the box

ANNEXURE 2

A. **Calculating the vaccine capacity** —The number of litres (1 litre = 1000 cms^3) of vaccine storage require may be calculated in the following steps..

1. List the main functions of the cold box or boxes: For example
   - — to supply the regional store with three months vaccine stocks
   - — to supply the district store with one months vaccine stocks
   - — to supply the mobile team with five days vaccine supplies
   - — to provide backup emergency store for district refrigeration facilities.
2. Calculate the number of doses of each type to be stored :

$$\text{No. of doses} = \frac{\text{No. Vaccinations} \times 100}{\text{percent usage}^*}$$

   * percent usage is 100 minus the percent wastage of vaccine estimated or observed.

3. Convert the number of vaccine doses to litres of storage capacity. For each vaccine type the packet size must be measured to obtain the number of cm^3 occupied by each dose :

$$\text{cm}^3 \text{ per dose} = \frac{\text{width} \times \text{length} \times \text{height in cms of packet}}{\text{No. of doses per packet}}$$

$$\text{litres storage required} = \frac{1.1^* \times \text{cm}^3 \text{ per dose} \times \text{no. of doses}}{1000}$$

   * 10% packing factor

If the size of the vaccine consignment is large it may be necessary to share it between two cold boxes. However, cold boxes are bulky and the greater the number of doses which can be accommodated in each box, the more economical will be the use of space in the vehicle

B. **Calculating the 'cold life' of the box**—The vaccines in the cold box will remain at temperatures just above freezing until all the ice packs have melted. So the length of the 'cold life' of the box in hours is determined by the speed at which the ice melts, the amount of ice and the size of the box.

The speed at which the ice melts can be controlled by the amount of insulation provided. This can be decided by the following steps :

1. Find the value A* from the table below.

Insulation type :	Litres capacity : 10	20	30	40	50	60	70
Felt	1.7	2.5	3.1	3.6	4.2	4.6	5.0
Glass wool	1.6	2.3	2.9	3.4	3.9	4.3	4.7
Foam polystyrene	1.5	2.2	2.7	3.2	3.7	4.1	4.4
Cotton wool	1.3	1.8	2.3	2.7	3.2	3.5	3.8
Still air	1.0	1.5	1.9	2.2	2.5	2.8	3.0
Rigid urathane foam	0.8	1.1	1.4	1.6	1.9	2.1	2.3

* The volue A is in joules per second per°C for one centimetre thickness of insulation. Litres capacity is adjusted to give 5 cms extra to each linear measurement to allow for the thickness of the ice packs.

The best insulation is given by rigid urethane foam and the least good insulation on this list is given be felt. The value 'A' is a measure at the speed of heat gain inside the box; the lower the speed, the better the insulation.

2. The value 'A' selected should be multiplied with the ambient temperature minus 4°C (thus, for an ambient temperature of +30°C the multiplier would be 26 to give value 'B').

3. Value 'B' should be multiplied by the number of 24 hour periods making up the 'cold life' of the box which you require, to give value 'C'. Allow a 'safety' margin of about 20% extra. If the box is going to be opened several times each day, allow an additional 33%. For example, a box with an intended cold life of 48 hours should be designed for 58 to 64 hours.

4. The table below gives the thickness of insulation required for each value of 'C' and capacity of cold box. The length of one internal dimension of the cold box cube is given at the base of the table.

		Litres capacity						
		10	20	30	40	50	60	70
	1500	52.5	34.5	27	22	19	17	15
	1400	49	32	25	21	17.5	16	14
	1300	45.5	30	23	19	16	15	13
	1200	42	27.5	21.5	18	15	13.5	12
	1100	38.5	25	19.5	16.5	14	12	11
	1000	35	23	18	15	12.5	11	10
	900	31.5	21	16	13	11	10	9
VALUE 'C'	800	28	18	14	12	10	9	8 *
	700	24.5	16	12	10.5	9	8	7
	600	21	14	11	9	7.5	7	6
than a thick limit	500	17.5	11.5	9	7	6	6	5
	400	14	9	7	6	5	4.5	4
	300	10.5	7	5	4.5	4	3	3
	200	7	5	3.5	3	4	2	2
	100	3.5	2.5	1.785	1.486	1.254	1.128	1
Litres of ice		7.3	11.3	14.4	17.3	20.3	22.8	25.7
Dimension of vaccine Storage Compartment		22	27	31	34	37	39	41.4

Centimetres thickness of insulation

This calculation assumes that the vaccine storage compartment is surrounded by 2.5 cms thickness of ice packs.

So to estimate the overall size of the cold box, add the following :

Example:—A cold box is needed to supply a district store with one months vaccine. The journey to the furthest district from the provincial health office is three days in temperatures averaging 35°C. The quantity of vaccine required is calculated as in A.2: the number of target population is 500:

(A.2)

			doses:
Measles	$\frac{500\times 100}{70}$	=	720
BCG	$\frac{500\times 100}{50}$	=	1000
Smallpox	$\frac{500\times 100}{65}$	=	770
DPT	$\frac{500\times 100}{90}$	=	550

A.3)	doses	packet size	doses/packet	cm^3 per dose	Total cm^3
Measles*	720	6×5.6×3	5	20.16	14 515
BCG*	1000	16×16×2	20	25.60	25 600
Smallpox	770	4×1.5×1.5	25	0.36	280
DPT	550	3×3×6.5	10	5.85	3 220
					43 610
*including diluent			say 50 litres× 1,1		47 980

(B.1)

It is decided to use foam polystyrene as an insulating material. Value 'A' is therefore 3.7 for a 50 litre container.

(B.2)

The ambient temperature has been estimated at 35°C;

$35\text{-}4=31\times 3.7=114.7$ (Value 'B')

(B.3)

Three days are required +1 as a safety factor:

$(3+1)\times 114.7=459$, or approximately 450 (Value 'C')

(B.4)

For 50 litres the table shows between 5 and 6 cms as the insulation thickness, 20.5 litres of ice and 37 cms dimension for the vaccine compartment. The outside dimension for the box will therefore be:

$37-(5.5\times 2)+(2.5\times 2)+(1.5\times 2)=56$ cms

Insulation — ice packs — Outer casing

ANNEXURE 3

PP. 501, PP. 502 and PP. 503 Rigid Urethane Foam Systems

Introduction:—These systems are two component, self-extinguishing, one-shot, liquid dispense systems. The systems are based on a Honeywill-Atlas sorbitol polyether. The use of these polyethers in the manufacture of rigid foam is the subject of British Patent 876, 469.

The Producer is Honeywill-Atlas Limited Mill Lane, Carshalton, Surrey, England. Telephone : 01-669 2261/4 Telex : 946833 Cable : Surfactant Sutton (Surrey). (The information which follows is drawn from the manufacturers information bulletin U/121. This does not infer that the World Health Organization endorses any particular manufacturer).

The systems are characterised by their low viscosity and excellent flow properties. The foam produced from these systems has fine cell structure, good humid ageing properties and complete dimensional stability at low temperatures. Each system is formulated to give foam with a core density in the range 1.9—2.1 lbs/ft³ (30.8—34.0 kg/m³) when used as follows :

PP. 551—Cavities up to 1½" (40mm) thick
PP. 502—Cavities of 2—3" (50—75mm)
PP. 503—Cavities of 4" (100mm) and above

Properties of Components of pp. 501, pp. 502 and pp. 503

Component A :—This component contains the isocyanate and has a shelf life of 6 months.

	PP. 501	PP. 502	PP. 503
Colour	Brown	Brown	Brown
Specific gravity 20/20°C	1.24	1.24	1.24
Viscosity at 20°C (poises)	4.9	4.9	4.9

Component B :—This component consists mainly of the polyether. It is formulated to produce a stable blended product with a shelf life of at least 6 months.

	PP. 501	PP. 502	PP. 503
Colour	Straw	Straw	Straw
Specific gravity 20/20°C	1.199	1.20	1.22
Viscosity at 20°C (poises)	2.0	3.5	5.0

Typical Properties of pp. 501, pp. 502 and pp. 503 Foam

Core density	1.9-2.1 lbs/cu. fit. (30.8-34.0 kg/m³)
Compressive strength	24 psi (0.165 MN/m²)
Tensile strength	16 psi (0.11 MN/m²)
K factor Btu/sq. ft/hr/(°F/in)	
Initial	0.115 (0.0166W/m°C)
Aged maximum (cut slab)	0.16 (0.023W/m°C)
Humid ageing at 70°C, 100% RH for 7 days, volume change	5.0%

Flammability :—These systems are rated as self extinguishing when tested to ASTM D 1692.

Overall Foam Densities—The core density should be in the range 1.9—2.1 lbs/cu. ft. (30.8—34.0 kg/m³) for these systems when used in the correct cavity size, eg. PP. 501 in cavities up to 1½" (40 mm) thick. Overall densities produced from these systems, or any other foam systems, will depend on a number of factors including the temperature, shape and general design of the article. It is therefore advisable before proceeding with a particular project to carry out trials with typical cavities under conditions to be encountered during the project, in order to determine density that will be obtained.

Use of PP. 501, PP. 502 and PP 503 in the Factory

Foam Component Temperatures :—It is recommended that these systems should be used with each component maintained at a temperature between 20 - 23° C. Foam can be produced at lower temperatures but higher densities may result.

Typical Processing Properties	PP. 501	PP. 502	PP. 503
Mixing ratio (by weight)			
Component A : Component B	1.0 : 1.1	1.0 : 1.05	1.0 : 1.0
Cream time secs	20—25	20—25	20—25
Rise time secs	120—130	120—130	120—130
Tack free time secs	130—140	130—140	130—140
Free rise core density lbs / cu. ft. kg. / m^3	1.45—1.6	1.8—2.0	2.0—2.2
	23.5—26.0	29.0—32.0	32.0—35.0

These properties apply with components used at 20° C.

Foam Production—Good quality foam can be produced by using the hand mixing technique but machine dispensing is the preferred method. In order to produce foam of the highest quality the foam equipments used will include :

(*a*) Accurate metering pumps capable of delivering requisite quantities of foam components to the mixing head.

(*b*) A suitable mixing head, capable of providing good mixing at all outputs.

(*c*) Foam Should be machine dispensed within the cream time.

Approval for Shipping and Buoyancy : The Dopartment of Trade and Industry has approved the use of PP. 503 for making internal buoyancy in life boats, life rafts and buoyant apparatus provided the user satisfies the Department in relation to specific applications.

Lloyds Register of Shipping has approved PP. 501, PP. 502 and PP. 503 for the insulation of refrigerated installations in ships cold stores and insulated and refrigerated containers, The approval is as usual provisional on the thickness and arrangements proposed by the insulation contractor, being approved in each case and the material being erected under the supervision and to the satisfaction of the society's surveyor. The foam must be covered with a fire resisting lining when installed. This was specified in the DTI notice M. 592 dated August, 1970.

Handling and storage of PP. 501, PP. 502 and PP. 503

Component A—The isocyanate in this component will react with water and generate gasious carban dioxide. Containers must therefore be kept closed when not in use, and should be stored under cool dry conditions where possible. All necessary precautions to exclude moisture must be taken. Slight pressure may develop if containers are stored under warm conditions, and they should therefore be opened with care.

All isocyanates used in polyurethane foams are liable to produce irritation of the lungs, and breething of the vapour should therefore be avoided. Also like all chemicals, it should not be allowed to come into contact with the skin.

It is recommended that goggles and gloves should be worn during handling, and that adequate ventilation should be provided to prevent accumulation of vapour. In the case of accidental contamination of the skin the area affected should be washed thoroughly with soap and water. For splashes in the eye, copious irrigation with water should be carried out immediately, and medical attention obtained.

Component B—Containers must be kept closed when not in use in order to prevent evaporation of blowing agent. Slight pressnre may develop if containers are stored under warm conditions, and they should

therefore be opened with care. Again it is recommended that goggles and gloves should be worn during handling. In the case of accidental contamination of the skin. the area affected should be washed thoroughly with soap and water. For splashes in the eye, copious irrigation with water should be carried out immediately, and medical attention obtained.

Foam production

This system is based on a low volatility isocyanate, and the vapour hazard is less than with foams based on TDI. Isocyanate is still evaporated from rising foam however, while in addition some atomisation of isocyanate may occur if air mixing equipment is used. Efficient ventilation should therefore be provided. In the absence of adequate ventilation, operatives should be provided with masks having a separate fresh air supply. If vapour build-up is only slight and occasional, simple organic vapour masks should be adequate.

Taps suitable For Component Drums

Taps and cradles for use in conjunction with the 45 gallon containers in which PP. 501, PP. 502 and PP. 503 are supplied are available from :

Taps
Buck and Hickman Limited,
Whitechapel Road,
London, E. 1.
Orders should refer to : Treacle tap 10558 D 3/4"

Cradles
Powell and Company Limited,
Cambrian Works,
Station Road, Burry Point,
Carmarthenshire.
Orders should refer to : Barrel stand and lifter, Model A. W.

Poliomyelitis and its control :—Poliomyelitis is an acute infectious disease, primarily of children, which affects the central nervous system and occurs both sporadically and epidemically. The aetiological agent has been identified as an enterovius-known as the poliovirus-with three distinct antigenic seroytypes, type 1, 2 and 3. The virus is rapidly inactivated by heat, desiccation, formalin chlorine and ultra-violet irradiation.

The incubation period, on an average is 17 days and the infection spreads through faecal to oral route. There are no non-human reservoirs for polomyelitis. It is primarily an infection of alimentary tract with the virus multiplying in the regional lymph nodes. There is no clinical evidence of infection unless the virus, after multiplying in the regional lymph nodes passes into the blood system and localises in the central nervous system. The laboratory investigations are suggestive that only a small percentage of infected persons suffer from a clinical disease and in only a miniority of these there is paralysis or meningo-encephalitis.

The laboratory diagnosis of poliomyelitis in a patient with an typical clinical picture can be established by virus isolation from stool and demonstration of an increasing antibody level in acute and convalescent phase sera. There is no specific treatment for the paralysis produced by poliovirus. In addition to the general supportive measures that are recommended in any acute infectious disease, physiothotherapy, must be initiated in the affected limbs immediately. *Prophylactically*, quarantine of contracts is not recommended and during an epidemic in addition to mass immunization the general protective and sanitary measures must be taken. Both over-crowding and surgical operations must be avoided during the epidemic. It

goes without saying that *phosiotherapy* is of vital importance in acute and convalescent phases and must not be ignored under any circumstances.

The oral poliovaccine (appendix—I) is most valuable as a prophylactic agent ; it has no curative value. The vaccine may be administered to anyone including infants at about 3—6 months of age. The only contra-indications for the administration of the vaccine are acute infectious diseases, high fever, vomiting and dysentery. Patients suffering from acute leukemia and lymphoma, generalised malignancy and receiving certicosteroides, antimetabolites may not be given the oral poliovaccines. One should avoid breast-feeding at least 4–6 hours before and 4–6 hours after the administration of the vaccine. Although There is no contra-indication to the use of multiple vaccines on the same day, no other immunizing agent other than the oral polio-vaccine be administered on a particular day. All the vaccines must be advised not to take hot water, hot milk or hot coffee for half-an-hour after the administration of the vaccine.

APPENDIX I

Oral Poliovaccine

The oral poliovaccine is comprised of the three serotypes of polioviruses. This is a living vaccine and its efficacy depends entirely on the administration of the live viruses to individual. If. some how are the other, any proportion of the living viruses. of any of the serotypes is inactivated. the vaccine ceases to be an effective immunizing agent. With the use of such vaccines which contain a significant proportion of inactivated virus one is actually achieving a false sense of security since the proportion of children who have been successfully immunized against poliomyelitis is very small.

To prevent the inactivation of the vaccine before administration to the children it is recommended that it should be stored at sub-zero temperatures. It is imperative that the suppliers, distributors and the poliovaccine clinics store this vaccine at 20° C. in a deep-freeze. In case, a deep-freeze is not available it might be stored in the freezing chamber of the refrigerator. During transport the vaccine must be kept either on dry ice (solid carbondioxide) or a freezing mixture.

At the polio-vaccination-clinic, the bottle containing the vaccine should not be frozen and thawed repeatedly since repeated freezing and thawing has a deleterious effect on the potency of oral poliovaccines. It would be preferable to keep the vials of the vaccine in ice during its administration to children. Every vaccine must be vaccinated with the appropriate volume of the vaccine. The person responsible for the distribution of vaccine in a clinic must ensure that the nurse is familiar with amount of volumes that have to be given to every child. In case. the vaccine is being administered by spoons, disinfectants like dettol or lysol may not be used for cleaning of spoons. The ideal way would be to boil the spoons in water and to cool the individual spoon in ice-water before the spoon is used for administration of poliovaccine to a child.

ADMINISTRATION OF ORAL POLIOVACCINE

Instructions for officials responsible for distribution of Oral Poliovaccine

Do's

1. Store the oral poliovaccine at sub-zero temperatures in the freezing chamber of the refrigerator or a deep-freeze.
2. Administer the appropriate quantity of vaccine by withdrawal from the vial through a sterilised syringe.
3. Sterilise the individual spoon, if used for delivery of vaccine drops, in boiling water or steam and *COOL* it completely for transferring the individual dose on to it.
4. Distribute at the vaccination clinic, a copy of the enclosed hand-bill (Appendix I) to all the parents. The hand-bill should better be translated to the local language
5. Maintain detailed records of vaccination including the Batch number of the vaccine vial used.

Don'ts

1. Do not freeze and thaw the vaccine container repeatedly.
2. Do not dilute the vaccine in water, milk or syrup before its administration to the child.
3. Do not sterilise the spoon, if used for delivery of vaccine drops, with any disinfectant like dettol, lysol or any other antiseptic.
4. Do not give oral poliovaccine in a hot, humid and crowded room. The vaccine should be given preferably in an air-conditioned room.

Do not administer any batch of oral poliovaccine unless you are sure that the vaccine was kept frozen, preferably in a thermocol box (obtainable from Mettur and Beardsell Ltd., Dhanur Building, S. P. Mehta Road, Bombay-1 or their-branches), during its transport to your organization/vaccination clinic. Ensure proper transportation by insisting on the transport of oral poliovaccine by the quickest available means af transport such as an aeroplane or a mail train. Both the supplier and the customer are equally responsible for ensuring a sub-zero temperature during the shipment of the vaccine. Ideally dry ice, obtainable from M/s. Sirdar Carbonic Gas Co. Ltd., 16, Apollo Street, Bombay or their branches), should be used. In case, dry ice is not available, a common salt-ice freezing mixture may well be used.

APPENDIX I

ADMINISTRATION OF ORAL POLIOVACCINE

Instructions for the parents

1. Administer oral poliovaccine to all children more than 3—6 months of age.
2. Administer three doses of the vaccine at monthly interval to protect the individual child adequately against poliomyelitis.
2. Do not give the vaccine to any child suffering from dysentery, diarrhoea, vomiting and fever.
4. Do not give oral poliovaccine to any child unless breast-feeding has been stopped for a period of at least six hours before as well as after the administration of the vaccine. During this period, feed the child artificially. Do not starve the child during this period.
5. Do not give hot drinks like tea, coffee or milk for a period of half-an-hour after the administration of the vaccine.

For potency testing of Poliovaccines or other related problems, contact :—

The Director,
National Institute of Communicable Diseases,
22 Alipore Road, Delhi-11 00 54.
(Phone ; 221531)

Organisation of Surveillance for Diseases which can be prevented by Immunization

The main objective of surveillance is to measure incidence of disease over time for taking needed preventive measures.

Elements of Surveillance

1. Data Collection

(a) Disease Recognition

Local name used for the disease by the community and their perception about the clinical manifestation of the disease has to be understand. Para-medical staff need training to ask suitable questions. and on the basis of answer will be able to come to interim diagnosis.

(b) Disence Reporting

Types of information to be reported and format

How frequently the report should be prepared and sent to whom.

'Nil' report has also to be sent,

2. Preliminary Data Analyse

Reporting efficiency—whether all the reporting units are sending the reports in time or not.

Is there any unusual event of morbidity and mortality in any area ?

3. Epidemiological Investigations

Extent of the problem—diagnosis of the cases, collection of specimen.

Source of infection and pattern of transmission—Line listing of cases.

Follow up of contacts.

Effectiveness of control measures.

Cases	*Immunized*	*Unimmunized*
Risk population		
Attack Rate		

Identify methods for future prevention,

4. Feed back

Publication of periodic surveillance newsletter.

Definition of some impotant Health Indices

1. Crude birth rate

$$\frac{\text{No. of live-births during a given Period in a given geographic area}}{\text{Estimated mid-period population of the given area during the same period}} \times 1000$$

2. Crude Death Rate

$$\frac{\text{No. of deaths during a given period in a given geographic area}}{\text{Estimated mid-period population of the given area during the same period}} \times 1000$$

3. Cause specific Death Rate

No. of deaths from a specified cause occurring among the population of a

given area during a given period
——————————————————— × 1000
Estimated mid-period population of the area during the same period

4. **Age spectfic Death Rate**

Total No. of deaths in a given age group
——————————————————— × 1000
Estimated total population in the same age group

5. **Sex specific Death Rate**

Total No. of deaths for the sex
——————————————————— × 1000
Estimated total population for the same sex

6. **Cause specific Death Ratio**

No. of deaths due to a specific cause during a given period
——————————————————— × 1000
Total No. of deaths due to all causes during that period

7. **Case fatality Rate of Death to case Ratio**

No. of deaths from a disease during a defined period
——————————————————— × 100
No. of new cases of that disease during the same period

8. **Infane Mortality Rate**

No. of deaths under one year of age among the population of a given area during a given period
——————————————————— × 1000
No. of live-births among the same population during the same period

9. **National Mortality Ratc**

No. of deaths under 28 days of age occuring in a given population during a given period
——————————————————— × 1000
No. of live-births occuring in the population during the same period

10. **Maternal Mortality Rate**

No. of deaths from maternal causes among the female population in an area in a given period
——————————————————— × 1000
No. of live-births in the area during the same period

11. **General Fertility Rate**

No. of live-births in one year in an area
——————————————————— × 1000
No. of women in age group 15-44

years in the same area during the same period

12. Sex Ratio at Birth

$$\frac{\text{No. of live born males during a period}}{\text{No. of live born female during the same period}} \times 1000$$

13. Incidence Rate

$$\frac{\text{Total No. of new cases of a specific disease occuring during a particular period}}{\text{Estimated population at risk during the same period}} \times 1000 \text{ (or 10,000 or 100,000)}$$

14. Point Prevalence Rate

$$\frac{\text{Total No. of cases currently existing for a specific disease during a given period of time}}{\text{Estimated population at risk during the same period}} \times 1000 \text{ (or 10,000 or 100,000)}$$

15. Morbidity Rate

$$\frac{\text{No. of sick persons in an area during a period}}{\text{Total population in that area}} \times 1000 \text{ (or 10,000 or 100,000)}$$

Statistical data presented below reflect the status of public healh service as it exists in a country during a particular period :—

1. Population ('000)	Male	283,940
	Eemale	264,020
	Total	547,960

2. %age Distribution of Population

Age Graup	*Male*	*Female*	*Total*
0—4	16.2	16.9	16.5
5–14	24.3	24.8	24.5
15–44	44.3	43.6	44.0
45+	15.2	14.7	15.0
	100.0	100.0	100.0

3. Total live Births ('000)

Male	11,940
Female	10,600
Total	22,540

Total Deaths ('000)

Male	5,524
Female	4,832
Total	10,356

Age-wisc Distribution of Deaths

Age-Group	*Total ('000)*
1	2,000
1—4	2,230
5—14	621
45+	5,373

(ii) Age-wise Distribution of Infair Deaths

Total Deaths ('000)

7 days	862
7—28 days	440
1—12 months	780

Distribution of Live-Births by Age of Mother

Age af Mother	*Total Live-Births ('000)*
15—19	2300
20—24	5765
25—29	5960
30—34	4325
35—39	2795
40—44	1375

6. The Number of maternal deaths that occured was 0.2 millions.

7. The following were no. of cases and deaths treated in hospitals due to a few communicable diseases :—

Diseases :	*Cases :*	*Deaths :*
Diphtheria	10,930	480
Enteric Fever	2,29,360	745
Poliomyelitis	9,206	190
Tetanus	59,800	6,900
T. B.	4,57,800	7,850
Whooping Cough	2,46,500	440

8. The distribution of the total number of deaths due to different causes for a given year is as follows :—

Diseases :	*No. of Deaths :*
Cholera	28,000
Plague	200
Smallpox	1,00,000
Dys. and Diarrohoea	8,25,600
Fevers	91,52,200
Accidents and Injuries	2,50,000

9. In a sample survey for morbidity conducted in a population 246,700,000 the following were the number of current cases (old and new) and new cases detected due to Annemia, T. B. (Pul.) and Rhumatism at the time of survey :—

Disease :	*(Old and New Cases) ('000)*	*New Cases :('000)*
Anaemia	52,055	10,411
T. B.	4,934	1,974
Rheumatism	4,385	3,947

Calculate the following :—

1. Crude Birth Rate.
2. Crude Death Rate.
3. Infant mortality rate.
4. Age specific death rate for the age-groups 0—4 years and 5—14 years.
5. Neonatal death rates.
6. Post-neonatal death rate.
7. Maternal mortality rate.
8. Case fatality rates for diphtheria, enteric fever, poliomyelitis, tetanus, tuberculosis, and whooping cough.
9. Cause specific death rates for cholera, plague, smallpox, dysentery and diarrhoera, fever, accidental injuries.
10. Incidence and point prevalence rates for anaemia, tuberculosis and rheumatism.
11. General fertility rate.

SOLUTIONS

1. Crude Birth Rate

$$\frac{22,540,000}{547,960,000} \times 1000 = 41.1$$

2. Crude Death rate

$$\frac{10,356,000}{547,960,000} \times 1000 = 18.9$$

3, Sex Specific Death Rate

(i) Male

$$\frac{5,524,000.}{283,940,000} \times 1000 = 19.5$$

(ii) Female

$$\frac{4,832,000}{264,020,000} \times 1000 = 18.5$$

4. Infant Mortality Rate

$$\frac{2,082,000}{22,540,000} \times 1000 = 92.4$$

5. Age Specific Death Rate

(i) 0—4 years.

$$\frac{4,362,000 \times 100}{547,960,000 \times 16.5} \times 1000 = 48.2$$

(ii) 5—14 years.

$$\frac{621,000 \times 100}{547,960,000 \times 24.5} \times 1000 = 4.6$$

6. Neonatal Death rate

$$\frac{1,302,000}{22,540,000} \times 1000 = 57.8$$

7. Post Neonatal Death rate

$$\frac{780,000}{22,540,000} \times 1000 = 34.6$$

8. Maternal Mortality rate

$$\frac{200,000}{22,540,000} \times 1000 = 8.9$$

9.Case Fatality rate

(i) Diphtheria

$$\frac{480}{10,930} \times 100 = 4.4$$

(ii) Enteric Fevers $\frac{745}{229,360} \times 100 = 0.32$

(iii) Poliomyelitis $\frac{190}{9,206} \times 100 = 2.06$

(iv) Tetanus $\frac{6,900}{59,800} \times 100 = 11.53$

(v) Whooping Cough $\frac{440}{246,500} \times 100 = 0.18$

10. Cause Specific Death rate

(i) Cholera $\frac{28,000}{547,960,000} \times 1000 = 0.05$

(ii) Smallpox $\frac{100,000}{547,960,000} \times 1000 = 0.182$

(iii) Plague $\frac{200}{547,960,000} \times 1000 = 0.0003$

(iv) Dysentery and Diarrhoea $\frac{825,600}{547,960,000} \times 1000 = 1.51$

(v) Fever $\frac{9,152,200}{547,960,000} \times 1000 = 16.70$

(vi) Accidents and injuries $\frac{260,000}{547,960,000} \times 1000 = 0.460$

11. Incidence rate

(i) Anaemia $\frac{10,411,000}{246,700,000} \times 1000 = 42.2$

(ii) Tuberculosis $\frac{1,974,000}{246,700,000} \times 1000 = 8.0$

(iii) Rheumatism $\frac{3,974,000}{246,700,000} \times 1000 = 16.1$

12. Point Prevalence Rate

(i) Anaemia $\frac{52,055,000}{246,700,000} \times 1000 = 211.0$

(ii) Tuberculosis $\frac{4,934,000}{246,700,000} \times 1000 = 20.0$

(iii) Rheumatism $\frac{4,385,000}{246,700,000} \times 1000 = 17.8$

13. General Fertility Rate $\frac{22,540,000 \times 100}{547,960,000 \times 44 \cdot 0} \times 1000 = 93.5$

14. Sex Ratio at Birth $\frac{11,940}{10,600} \times 100 = 112.6$

Training Programme At The State Level

1. Fixation of date—durations of the training will be 5 days.

2. Venue of the training—In case of big states like U.P., Bihar, M.P. State healh authorities may like to organise at divisional HQs in batches.

3. List of participants—key persons from the district health office and Corporation should be invited.

4. Faculty of the training session—State programme officers dealing with maternity and child health, tuberculosis, smallpox,, rural health and paediatricians have to be involved.

5. Time table :

   a. One hour on the first day should be kept for inaugural session involving Health Minister and Health Secretary,

   b. DMHS should be requested to be present in sessions which deal with administrative matters.

   c. Broad distribution of EPI and Malaria may be ratio of 4:1

   d. Field visit to an immunization session should be included

6. Arrangement for settlement of administrative matters like payment of TA and DA to participants and distribution of training materials should be pre-arranged.

No. T. 13012/1/78-EPI

Form

The Director General of Health Services

To

The Director of Health Services of all States and Union Territories

New Delhi, the 15 February 1978.

Sir,

The combined meeting of the Director of Health Services and the State EPI Officers was held on 1st February 1978 which was followed by a seminar of EPI Officers upto 6th February on retraining of the erstwhile NSEP staff to take up their new duties including immunization and malaria control. It was decided in this meeting that a programme of orientation will be arranged at the State level (divisional leval in case of big states like U. P., M. P., Maharastra and Bihar, where two officers from each district Regional Directors and Corporation Officers will participate. This will be followed by training programme at the district level where one medical officer and NSEP Staff (vaccinator, health superviser, PMA) from each PHC and Municipality Health Officer will participate. Training at the district level may have to be conducted in batches.

I am enclosing herewith the guidelines of the training programme at the state and district level which were prepared by the State EPI Officers attending the seminar. These guidelines are flexible and can be modified to suit the local conditions.

I shall request you to nominate the officers who will act as Chief Co-ordinator of this training programme who may be asked to plan and indicate the requirement of fund. WHO will bear the cost of travel and perdiem of the participants and contingency expenditure in connection with the training programme. A Central Officer will be available to assist you in the training programme at the state level. I am enclosing herewith a proforma which may kindly be filled up and sent to this Directorate so that necessary fund can be made available.

I hope with your administrative support the training of all the NSEP staff in Immunization and malaria control will be completed by May 1978.

Yours faithfully

(R. N. BASU)

For—Director Gen. Of Health Services

Copy to Joint Director/Deputy Director/Assistant Director of Health Services incharge of Expanded Programme on Immunization of all states and U. Ts.

Information required regarding re-training of NSEP staff at state level for District and Corporation officials and at District Level for MO—PHC and NSEP Staff.

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1. Likely date (duration of the training will be five days) of training at State and District level.
2. Approximate number of the participants-State Level-District Level.
3. In case of big states (viz. U. P., M. P., Bihar, Rajasthan and Maharastra) do they like to organize on regional/divisional basis? If so, places may be indicated with dates and likely number of participants to be trained at each regional centre.
4. Name of officers who will act as Chief Co-ordinator for the States.
   (Money from the Ministry of Health, Department of Health, Government of India will be sent in his name to bear the expenditure of training and he will have to submit the accounts to the Department of Health, Ministry of Health and Family Welfare, New Delhi through the D. H. S. of the State).
5. Requirements of fund with broad break up.
6. Any other information.

Training At The State Level

1. Participant.—Two officers from each district, Regional Directors and Corporation Health Officers will participate in the orientation at the State level. In case of big cities like, U. P, M. P., Maharastra and Bihar the State Health authority may like to organise the training at divisional level.

2. Duration of training.—Suggested duration of training is 5 days but the State Health authority may fix between 3 to 5 days considering administrative conveniences.

3. Faculty.—Regional Co-ordination Officer (Malaria), Director, Drugs controller, State Programme Officers for malaria, tuberculosis, MCH, health education and paediatricians from medical colleges will form the faculty of this course.

4. Curriculam.—The programme will follow the pattern as conducted at the Central level. The items which should be covered are :

a. Concept of expanded programme on immunization
b. Analysis of the health problems of the state and selection of priority
c. Principles of immuniology in prevention of communicable diseases-immunization schedule
d. Surveillance of preventable diseases-data collection, epidemiological investigation and survey outline
e. Steps in Planning and execution of EPI
f. Vaccine handling—system of storage and distribution of vaccine.
g. Epidemiology of the diseases which can be prevented by immunization.
h. Role of health education in immunization and malaria control.
i. Evaluation of programme—record keeping and analysis of data.
j. Field visit to urban and rural centres where immunization activities are carried out.
k. Modified plan for malaria control and role of NSEP staff in surveillance operations.

Budget—The actual travel cost as per State Government rules and per diem will be paid by WHO. The rate of per diem is Rs. 50 but in case of officers residing at the State headquarter (where training is being conducted) will be Rs. 20/-. Contingency for preparation of training materials and other petty expenditure will not exceed 10% of the above total budget.

Training at the District Level

1. **Participants** - One Medical Officer and NSEP staff (vaccinators and Health Supervisors) from each PHC and PMA at the district level will attend the session. On an average there are three or four vaccinators and one Health Supervisor in each PHC and two PMA in each district. The Municipal Health Officer and their NSEP staff should also be involved in the training. It is desirable that the number of participants do not exceed 30 in number in one batch.

2. **Place of training**—The training should be conducted at the district Head quarter either in the District Health Office or Regional Training Centres. The whole training should be conducted in one place.

3. **Faculty**—Health Officials at the district level viz. MMOH District Malaria Office, District TB Officer, Mass Media Officer and the Superintendent of the Hospital, Professor of Paediatrics and Obstetrics and Gynaecology of Medical College (if located within the district), will act as faculty of the course.

4. **The curriculam content**—Total duration of training is 5 days whereas the first three days will be joint programme for Medical Officers and para-medicals. During this period the first two days will be lecture-discussions and third day will be mainly practical demenstrations. Next two days will be entirely for the para-medicals where emphasis will be given on disease recognition and demonstrations. The suggested items which should be covered day by day are as follows :

First day.

1. Involvement of the administrator viz. District Magistrate, MMOH and others
2. Concept of Expanded programme on Immunization
3. Analysis of the health problems of the district and selection of priority
4. Principles of immuniology in prevention of communicable disease—immunization schedule
5. Planning and execution of programme—setting objectives, targets.
6. Procurement, storage, supply and use of Vaccine.

2nd day.

1. Surveillance of diseases, preventable by immunization
2. Modified plan of malaria control
3. Role of PHC MO and NSEP staff in malaria control
4. Role of health education in EPI and malaria control
5. Field management, supervision, record keeping, working schedule etc.
6. Compilation and analysis of data, and evaluation of programme.

3rd day

1. Field demonstration on immunization practices and collection of blood slides.
2. Survey of some diseases in the field and schools.

4th day (only for NSEP staff)

Demonstration of clinical cases like diptheria, whooping cough, tetanus, followed by discussions.
Field demonstrations

5th day (only for NSEP staff)

Discussions on diseases like malaria Tuberculosis, Polio and measles followed by demonstrations and discussions.

5. *Follow on of the NSEP staff in their respective PHCs :*

1st day

Preparation of the community for the programme by meeting leaders and carrying out educational activities

2nd day

Observations of records maintained at PHC/sub-centres and survey in the field on morbidity, mortality, immunization status and community knowledge.

3rd day

Field practice on immunization and blood slide collection and filling up the forms

4th day

Field practice on immunization and blood slide collection and filling up the forms

5th day

Final discussions with PHC medical officers and NSEP staff and clarification of any doubts.

6. Budget

The actual travel cost (as per State Government rules) and per item will be paid by WHO. The per diem will be Rs. 25 for M.O, and Rs. 10 for the M.O. Municipal H.O. whose headquarter is at the same place where training has been organized. For NSEP stalf (P M.A. Health Supervisors and Vaccinators), a stipend of Rs. 75/ for the total period (5 days at district and 5 days at P.H.C.) will be paid. The contingency expenditure will be limited to a ceiling of 10% of the above budget.

Training Programme At The District Level

1. Decision to be made about number of batches of training to be conducted and fixation of their days.
2. Listing of participants in each batch one PHC doctor, vaccinators, vaccination supervisor and the PMA
3. Duration of training-two days for all participants followed by three days for only NSEP staff .
4. Venue of the training has to be decided.
5. Faculty.District TB officer, FW Officer, Malaria Officer should be actively involved. Some State officer shouid be present in as many districts as possible.
6. Time table :
   a. District Magistrate and Municipal Health authority shouid be involved
   b. PHC doctor should be so oriented so that hc can arrange for follow up training of the NSEP staff.
   c. Practical exercise of BCG and DPT immunization have to be arranged.
7. Administrative matter like disbursement of the TA and DA of the participants has to be pre. planned.

TRAINING AT THE DISTRICT LEVEL

1. **Participants**—One Medical Officer and NSEP staff (vaccinators and Health Supervisors) from eachP HC and PMA at the district level. On an average there are three or four vaccinators and one Healh Supervisor in each PHC and two PMA in each district. The Municipal Health Officer and their NSEP staff should also be involved in the training. It is desirable that the number of participants do not exceed 30 in number in one batch.

2. **Place of training**—The training should be conducted at the district Headquarter either in the District Health Office or Regional Training Centre. The whole training should be conducted in one place.

3. **Faculty**—Health Officials at the district level viz. MMOH District Malaria Officer, District TB Officer, Mass Media Officer and the Superintendent of the Hospital, Professor of Paediatrics and Obstetrics and Gynaecology of medical college (if located witnin the district).

4. **The curriculum content**—Total duration of training is 5 days whereas the first three days will be joint programme for medical officers and para medicals. During this period the first two days will be lecture discussions and third day will be mainly practical demonstrations. Next two days will be entirely for the paramedicals where emphasis will be given on disease recognition and demonstrations. The suggested items which should be covered day by day are as follows :

First day

1. Involvement of the administrator viz. District Magistrate, MMOH and others;
2. Concept of Expanded programme on Immunization.
3. Analysis of the health problems of the district and selection of priority
4. Principles of immunology in prevention of communicable disense–immunization schedule
5. Methods of organization and implementation of the programme-procurement, storage, supply and use of vaccine.
6. Planning and execution of programme-setting objectives, targets.

2nd day

1. Surveillance of diseases, preventable by immunization
2. Modified plan of malaria control
3. Role of PHC, Mo and NSEP staff in malaria control
4. Role of health education and EPI and malaria control
5. Field management
   supervision, record keeping, working schedule etc.
6. Compilation and analysis of data and evaluation of programme.

3rd day

1. Field demonstration on immunization practices and collection of blood slides.
2. Survey of some diseases in the field and schools.

4th day (only for NSEP staff)

Demonstration of clinical cases like diphtheria, whooping cough, tetanus, followed by dicsussions Field demonstrations

5th day

Discusssions on diseases like malaria, Tuberculosis Polio and measles followed by demonstrations and discusssions.

5. Follow up of the NSEP staff in their respective PHCS

Ist day

preparation of the community for the programme by meeting leaders and carrying out educational activities

2nd day

Observation of records maintained at PHC/sub-centres and survey in the field on morbidity, mortality, immunization status and community information.

3rd day

Field practice on immunization and blood slide collection and filling up the forms

4th day

—do—

5th day.

Final discussions with PHC medical officers and NSEP staff and clarification of any doubts.

Organisation of Surveillance for Diseases which can be Prevented by Immunization

The main objective of surveillance is to measure incidence of disease over time for taking needed preventive measures.

Elements of Surveillance

1. Data Collection

(*a*) **Disease Recognition**—Local name used for the disease by the community and their perception about the clinical manifestation of the disease has to be understood. Para-medical staff need training to ask suitable questions, and on the basis of answer will be able to come to interim diagnosis.

(*b*) **Disease Reporting**

Types of information to be reported and format

How frequently the report should be prepared and sent to whom.

'Nil' report has also to be sent

2. Preliminary Data Analysis—

Report in efficiency-whether all the reporting units are sending the reports in time or not. Is there any unusual event of morbidity and mortality in any area ?

3. Epidemiological Investigations

Extent of the problem—diagnosis of the cases, collection of specimen.

Source of infection and pattern of transmission-Line listing of cases.

Follow up of contacts.

Effectiveness of control measures.

Cases	*immunized*	*Unimmunized*
Risk population		
Attack Rate		

Identify methods for future prevention.

4. Feed back—

Publication of periodic surveillance newsletter.

Evaluation of Programme—

Evaluation should answer the questions, (*a*) To what extent the objectives of the programme are being achieved and (*b*) How should the programme modify its operations in order to be more successful.

Aspects of Evaluation—

(*a*) **Diseasc surveillance.**

(i) Reporting Efficiency

(ii) Investigations and Survey.

(*b*) **Vaccine Potency**

(i) Upon receipt from the manufacturer

(ii) In case of outbreak of disease in population thought to be immunized.

(iii) Discovery of breakdown in cold chain

(c) Evaluation of coverage

(i) Selection of village using statistical sampling technique

(ii) Examination of children

	3—8 month																			
Child	M	M	D 1	D 1	D 2	D 2	D 3	D 3	B	B	}	9—14 month							15—20 month	
No.	O	V	O	V	O	V	O	V	O	V	}									

(d) Evaluation of management and operation

(i) Supervision, training, job-description of staff.

(ii) Immunization session-number of vaccinations, vaccination technique, vaccine wastage,

(iii) Storage and distribution of vaccine,

(e) Evaluation of Health Education

(i) Methods used-personal contact, group meeting

(ii) Materials used

(iii) Message given

(iv) Staff skill in educational practice,

Expanded programme on Immunization

Children are the most valuable asset of our country and child welfare is and integral part of socral justice. National development plans are aimed at providing better life to the people of tomorrow. These development plans lap emphasis on child health, especially, prevention of infectious diseases.

In this direction, efforts are afoot to initiate a Centrally sponsored scheme of Expanded Programme on Immunization (EPI) during the Sixth Five, Year Plan. A Section of EPI has been created in the Directorate General of Health Services, Ministry of Health & Family Welfare. The Assistant Director General of Health Services, who was earlier incharge of National Smallpox Eradication Programme, will look after this new unit. The unit will co-ordinate various components of EPI, viz. distribution of quality vaccine, development of surveillance system, organization of cold chain for storage of vaccine, integration of different immunization activities, training of erstwhile smallpox staff to take up new assignment and periodic assessment of the ongoing programme.

The ultimate objective of the programme is to reduce the incidence of the diseases of diphtheria, whooping, cough tetanus, poliomyelitis, tuberculosis (miliary and meninglal) and measles by the end of Sixth Five Year Plan, so that these diseases do not remain major public health problems. The programme will be permanent 'ongoing progamme for children and will be implemented through the existing delivery system, viz. Primary Health. Centres and Sub-Centres in the rural areas and hospitals and dispenseries in the urban areas. The country will be made self-sufficient in the production of different vaccines to meet the requirements of the programme.

For technical review of the countrywide programme of EPI two working groups have been constituted by the Ministry of Health and Family Welfare. These are :

(*a*) The Working Committee for the Integration of Immunization Programme, and

(*b*) Vaccine Production Board. These Groups comprise all concerned programme officers, Directors of vaccine production institutes, experts from international agencies and other relevent institutions.

Working Committee for Integration Imminization Programme

The working committee constituted for the execution of the Integrated Immunization Programme has the following members :—

1.	Dr. Ranjit Sen Deputy Director Ceneral (Planning) Directorate General of Health Services.	Chirman
2.	Dr. E. V. Sebastian Deputy Commissioner (MCH) Department of Family Welfare.	Member
3.	Director Central Research Institute Kasauli.	Member
4.	Director National Institute of Cormmunicable Diseases Delhi	Member
5.	Dr. Shanti Ghosh Sr. Paediatrician, Safdarjang Hospital New Delhi.	Member
6.	Dr. (Kumari) S. Gupta Professor of Paediatrics Maulana Azad Medical College, New Delhi.	Member
7.	Under Secretary Department of Health dealing with Rural Health Services	Member
8.	Under Secretary Department of Health dealing with Public Health.	Member
9.	Advisor T. B., Directorate General of Health Services New Delhi.	Member
10.	Assistant Director General (H. A) Directorate General of Health Services New Delhi.	Member
11.	Assistant Director General (EPI) Directorate General of Health Services New Delhi	Member Secretary

The UNiCEF is represented by Dr. J. P. Greaves, Senior Programme Officer, Mr. A. N. Khlystov, Programme Officer (Health and Nutrition Section) and Shri V. Radhakrishanana, Programme Assistant Health and Nutrition Section).

Dr. S. Tomaszunas, Medical Officer incharge of Expanded Programme, on Immunization, and Dr. G. S. Tawil, Regional Advisor in the Health Laboratory Services, are the representatives of the W. H. O.

The terms reference of the working committee are as follows .

(i) To fix the annual targets of coverage of mothers and children under the immunization programme.

(ii) To frame immunization schedules and undertake periodic review of the same.

(iii) To review the progress of the programme at the State and Central level.

(iv) To lay down the methodology of evaluation of the technical aspects of the immunization programme through serological survey, storage and distribution.

(v) To supervise the orientation training programme at the State and Central level.

(vi) To undertake field visits to verify the actual implementation of the immunization programme.

(vii) To prepare annual report for submission to the Ministry of Health and Family Welfare about the progress and problems of the programme.

First Meeting of the Committee :—The first meeting of the working Committee was held in Nirman Bhawan on 14th September . 1977 under the chairmanship of Dr. Ranjit Sen. Deputy Director General of Health Services. Items discussed in this meeting included review of the immunization schedule ; review of availability of DPT, DT, TT veccines at Haffkine Institute. Bombay and C. R. I. Kasauli : coverage of DPT vaccination for 1977-78 and 1978-79 ; coverage of TT (Tetanus) veccine for pregnant mothers : Smallpox primary vaccination status, BCG production, coverage, targets etc ; and introduction of Measles and Polio vaccines In the immunization programme-scope and coverage. The meeting formulated a schedule of immunization.

Programme Officers for E. P. I.:—All the State Governments have been asked to identify an officer of the rank of Assistant/Deputy/Joint Director of Health Services for designating him as 'Programme Officer for E. P. I.' in their respective States. The programme officer will givefu ll-time attention in co-ordinating all immunization activities at the State-level. The suggested functions of the EPI Unit at State level are :—

(*a*) Formulate the strategy, priority and operational target of the programme on annual and plan period basis. Co-ordinate with various departments who are participating or contributing in the immunization programme.

(*b*) To develop a surveillance system to get adequate information about the indices of childhood diseases which can be prevented by immunization.

(*c*) Integration of the delivery of the immunization services through Primary Health Centres and subsidiary health centres in the rural areas and hospitals and dispensaries in the urban areas

(*d*) Arrangement of training of staff who will be engaged in immunization programme.

(*e*) Procurement and distribution of veccines to the district and other peripheral Units ensuring that the vaccines do not loose their potency during storage and transport. This requires organization of cold chain.

(*f*) Periodic assessment of the programme regarding coverage and its impact on the incidence of the preventable diseases through routine reports and special surveys.

(*g*) Collect reports and returns from the districts and other agencies for consolidation and review. The monthly report has to be sent to the Centre for keeping liaison and necessary assistance.

The following States/Union Territories have so far nominated their programme Officers for Expanded Programme on Immunization :—

1.	Dr. G. V. Mohana Reddy	Andhra Pradesh
2.	Dr. N. D. Palkar	Maharashtra
3.	Dr. B. B. Purohit	Orissa
4.	Dr. M. V. Rajgor	Gujarat
5.	Dr. K. G. Kularni	Karnataka
6.	Dr. V. D. Angami	Nagaland
7.	Dr. T. S. Sahai	Rajasthan
8.	Dr. A. K. Heldar	West Bengal
9.	Dr. K. Ker	Shillong
10.	Dr. Ananda Heleker	Goa, Daman & Diu
11.	Dr. S. P. Kapoor	Himachal Pradesh
12.	Dr. Surandra Manglik	Uttar Pradesh
13.	Dr. S. R. Halder	Andaman & Nicobar Islands
14.	Dr. K. P. Dutta	Delhi
15.	Dr. Pandit Ranga Rao	Lakshadweep Kavaratti Island
16.	Dr. N. P. Kackria	Chandigarh
17.	Dr. A. Pazo	Sikkim
18.	Dr. T. M. Khan	Madhya Pradesh

A Seminer on orientation of the State Programme Officers for E. P. I. for retraining the National Smallpox Eradication Programme staff is being held at the National Institute of Communicable Diseases, Delhi from 1st February to 6th February, 1978. A joint meeting of Directors of Health Services of States and E. P. I. Officers is being held on 1st February, 1978. The delegates have been requested to bring along-with them information about current immunization activities being carried out in their respective States or Union Territories which will provide the baseline date for planning the future programme.

Training of National Smallpox Eradication Programme Staff :—About 28,000 smallpox staff, viz., para-medical Assistants Health Supervisors and Vaccinators will be trained to take up the new assignment of multipurpose workers including E. P. I. This training will be conducted with the financial assistance from WHO/ SIDA. E. P. I. programme officers who will be given necessary orientation at Delhi from 1st to 6th February, 1978 will then co-ordinate the training programme of the district and corporation officials at the States level during February-March, 1978. District officials will concuct the training of PHC Medical Officers and Smallpox staff in batches during March to June, 1978.

Some Data About Vaccine Production

(*a*) **D.P.T.** : The following quantity of UPT vaccine will be available to National Immunization Programme from two manufacturing Institutes namely Central Research Institute, Kasauli and Haffkine Institute, Bombay.

1977-78	—	10.5 Million doses
1978-79	—	13.5 ,,
1979-80	—	19.0 ,,

(*b*) **Frceze Dried Smallpox Vaccine** :—During 1977-78, the two vaccine Institutes, one at Belgium (Karnataka) and other at Patwadangar (Uttar Pradesh) are producing Freeze Dried Smallpox Vaccine. The present stock of veccine in the Institutes is 7.4 million ampoules (111 million doses). Considering the diminished requirements of Vaccine, from 1978 only patwadangar Vaccine institute will produce Smallpox vaccine on a limited scale.

(*c*) **B. C. G. Vaccine** : –B.C.G. Vaccine Institute, Guindy (Tamil Nadu) has the capacity to produce 50 million doses in the current year. More then ten million doses are in stock now, as the demand from the field has not yet picked up.

Prcsent Coverage (in million)

Year	Smallpox (Primary)	BCG	D.P T. (including second doses)
1974	24.1	12.0	1.0
1975	19.0	12.8	2.4
1976	10.6	13,8	3.6

It will be seen that, after the achievements of zero smallpox incidence, primary vaccination has declined to a great extent.

Current Munization Activities In Maharashtra State

Census Population 1971 — 50412000

1. Mid-year estimated population 1971 — 58005000
2. Latest Birth rate 1976 — 31.0 Death rate — 11.2 (1976)
3. Infant Mortality rate 1976—71 Material Mortality Rate-2 (1976)
4. Average Household size 1971 census) — 5.9
5. Incidence of the disease

Source : (Municipal Corporation & District Hospitals 1965)

	Disease	Indoor Patients	Outdoor Patients	Deaths amount indoor	patients
1	Pertusis	599	11533		31
2.	Diphtheria	1277	3110		146
3.	Tetanus	6489	5764		2094
4.	Tuberculosis	29677	127915		2992
5.	Measles	899	6935		128
6.	Poliomyelitis	622	2247		25

6. Staff responsible for different Immunization activities :

Rural and Urban Areas—Smallpox Vaccination—Vaccinators. —B.C.G. Technicians } Under supervision of

—B. C. G.

—D. P. T. —M.C.H.& Family Planning staff. } Medical Officers

At present these are the only vaccinations which are given regulary in rural areas and urban areas. Polio vaccine is given on voluntary basis sometimes. And when given, M.C.H. staff is mainly engaged in the administration of the vaccine. In Municipal Corporations, health staff is engaged in this programme.

Average percentage of total time of staff given for immunization is 10—15 per cent.

7. Present drrangement of Training and Supervision :

(*a*) Training :

Vaccinators :—They are given training in the technique of vaccination before they are employed in the service. They work in the field as trainees under senior vaccinators and are supposed to do 400–500 vaccinations with at least 200 primary vaccinations.

B. C. G. Technicians:—After their selection as technicians, they are given training at Tuberculosis Control and Trainfng Centre, Nagpur, and J. J. Group of Hospitals. Bombay, for one month. After successful training the technicians work under the close supervision of the team leader and the Medical Officer of District T. B. Centre.

M. C. H./Family Planning Staff:—The Auxillary Nurse Midwives under these programmes learn the technique of injection during their training course only. They are mostly engaged presently in DPT/ DT and Tetanus Toxoid Immunization Programme.

The above training arrangement is for the regular immunization programme which is done routinely. But as envisaged in the extended programme of immunization and which is launched in the State in every Primary Health Centre of 5 Multi-purpose workers Districts and one Primary Health Centre each from the remaining 20 districts of the State where all the above immunizations are to be carried out by Multi-purpose Workers following training programme has been evolved.

1. **Smallpox Vaccination** :—The Multi-purpose Workers other than previous vaccinators are being given training under Expanded Programme or Immunization at the Primary Health Centres for smallpox vaccinations.

The training is given by Sanitary Inspectors at Primary Health Centre having good experience under the supervision of Senior Sanitary Inspector. A batch of 20 workers is taken at a time to whom training is given for 15 days. The worker is treated successfully trained after he has performed sufficient number of Primary and Revaccinations using the bifurcated needle technique under close supervision in the field.

2. **B.C.G. Vaccination:**—The training to the Multi-purpose Workers is being imported by the BCG Technicians at present working in the BCG Mass Campaign. One BCG Technician is responsible for training Multi purpose Workers of three Primary Health Centres. 22 Multi-purpose workers of Primary Health Centre, will be taken up at a time. Within a primary health [centre one male and one female—Multi-purpose workers are trained together for about 2 weeks in the area of their allotment. During the training period the BCG Technician resides in the headquarter village of the Multi-purpose Workers. The training in the theoretical aspects of BCG Vaccination and demonstration of some procedures (Sterilisation, reconstitution of vaccine, etc.) ls given to two teams of male and female Multi-purpose Workers by Medical Officer, Primary Health Centre and BCG Technician for one day at the centre.

The practical training of BCG Vaccination is given in the village population. During practical training, children 0-19 years of age vaccinated. While vaccinating them, the BCG Technician imparts training to both the workers. For this, BCG Technician first makes Multi-purpose workers watch him work for a day or so. Starting with children above 15 years of age, the trains the Multi-purpose Workers in the technique of BCG Vaccination in children between 10 and 19 years age and finally those under 1 year of age.

In about 5-8 days time most of the Multi-purpose Workers are able to give BCG intradermally. Initially, the Multi-purpose workers vaccinate the small children under supervision of the trainer to avoid complications.

The total length of training (theoretical and practical) for each pair of Multi-purpose Workers is 15 days. In this way, one BCG Technician can train in 2 teams of male and female Multi-purpose Workers in a month. All the Multi-purpose Workers in a Primary Health,Centre can thus be trained in a period of 6 months.

3. **DPT/T. T. Immunization** :—Non-MCH/Family Planning Multi-purpose Workers require the training in the technique of Injection giving. Two such Multi-purpose Workers are trained at a time at the Primary Health Centre by the Medical Officer himself for a period of 7 days. All aspects of injection technique are taught including selection of site, sterilisation, etc.

Supervision : During the routine programme of various immunizations they were supervised by respective supervisors for the programme at Primary Health Centre level and district level. Supervision now envisaged in the M. P. W. Scheme would be in following phases:

(i) Preparatory

(ii) Attack

(iii) Consolidation

(iv) Maintenance.

Preparatory Phases : The Multi-purpose Workers will enumerate the beneficiaries and the supervisors will guide the workers. Health Education of the people regarding immunization and its importance and finalising the dates of first doses.

Attack Phase: Actual immunization time-table of the workers in the villages of their charge will be worked out by supervisors and they will concurrently supervise the work of various immunizations being given in the field.

Consolidation Phase : Supervisors will verify the list of beneficiaries and identity those beneficiaries who were not given the 1st dose (or subsequently 2nd or 3rd dose) and in follow-up action persuade such drop-outs to be brought under the fold.

Maintenance Phase : The supervisors will keep a watch on the new borns to be immunized. (This phase will be hopefully reached in a year or so in most of the villages). Later he will chart out similar immunisation programme for them and get it executed through his Multi-purpose Workers.

(8) ***Immunisation Schedule*** :

The schedule given by Government of India is followed in the State; under Expanded Programme of Immunisation, the following schecule has been worked out :

0-5 Years

After 3 months age — I dose DPT + Primary vaccination
(Interval 14 to 8 weeks) II dose DPT
III dose DPT + B.C.G- Vaccination

Note : All children in this age group above the age of 3 months will be covered.

Pregnent Mothers :

After 16 weeks of pregnancy ... I dose Tetanus Toxoid
(At 4 to 6 weeks interval) ... II dose Tetanus Toxoid
III dose Tetanus Toxoid

9. Institutions :

Rural

1. Primary Health Centre
2. Zilla Parishad Allopathic dispensaries.
3. Rural Hospitals

Urban

1. Teaching Hospitals
2. Municipal Hospitals
3. District Hospitals
4. Cottage Hospitals
5. Voluntary Organisation Centres
6. General practitioners.

The detailed information about the voluntary organisations and general practitioners (the non-Governmental agencies) is called for from the districts.

Facilities available :—Facilities available in the Governmental institutions are adequate so for as refrigerators, syringes, needles, etc., are concerned. However, BCG facilities are limited.

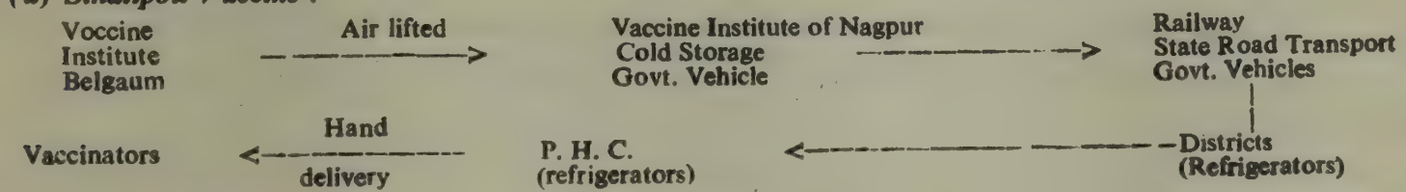
10.

		1976	1977
(*a*)	Smallpox Primary	19,13,928	12,96,588 provisional
	Revaccination	46,52,705	16,68,221 provisional
(*b*)	DPT	(1976-77)	(1977-78 upto December)
	1st Dose	Not available	Not available
	2nd Dose	4,07,835	5,22,100
	Broster		1,74,215
(*c*)	*Tetnus Texoid*		
	1st Dose ...	Not available	Not available
	2nd Dose ...	1,45,316	1,76,005
(*d*)	*Poliomyelitis* :	Programme not so far undertaken by the State Government.	

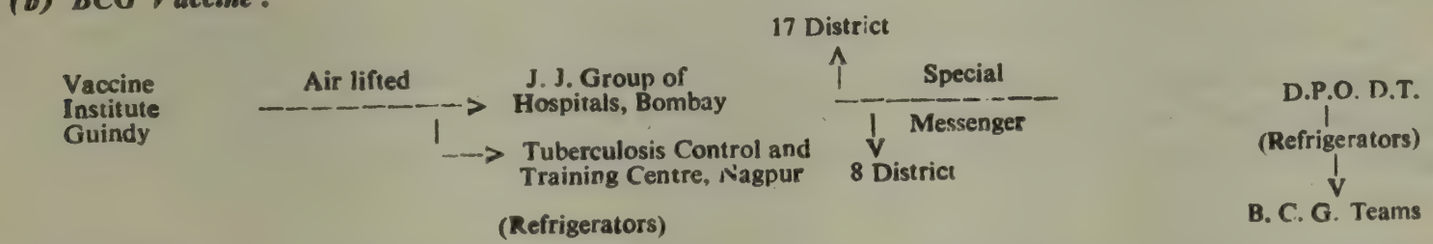
N. B. : In the State only 2 doses schedule was followed till recently for DPT and T.T. and hence no figures are given for 3rd dose.

Current Procedure of Procuring Vaccine and Transporting

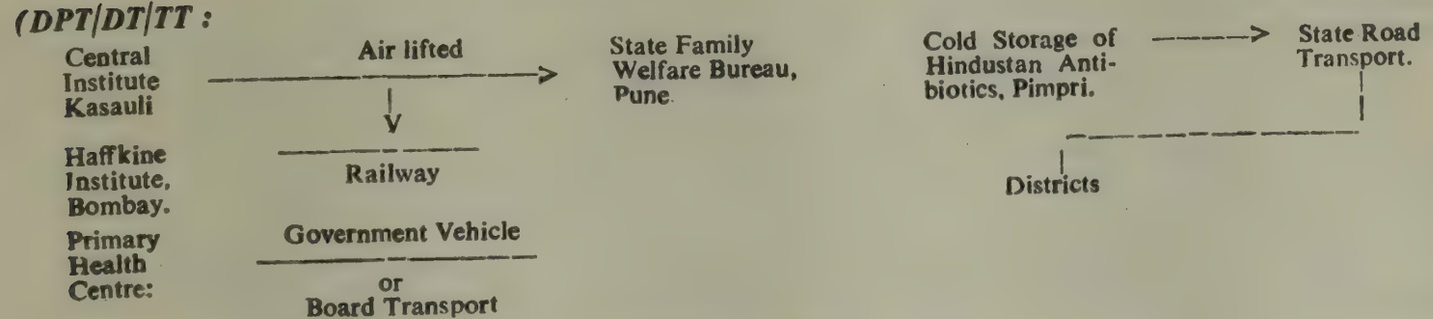
(a) Smallpox Vaccine :



(b) BCG Vaccine :



(DPT/DT/TT :



Methods of Storage

Smallpox vaccine :

A. State level—Cold storage of Vaccine Institute, Nagpur.

B. District level—Refrigerators

C Primary Health—Refrigerators

D. Workers—Vaccine for 2 weeks only which does not deteiorate at room temperature for that period is supplied.

BCG Vaccine :

A. State Level—In refregerators at J. J. Group of Hospitals, Bombay and T. B. Centre, Nagpur.

B. District level—Refrigerators District Tuberculosis Office.

C. P. H. C. level—Refrigerators

D. Workers—Vaccine ampoules are wrapped in double black cloth over which water is poured from time to time till it is consumed. Vaccine is well kept away from direct or indirect light in dry and dark cool place.

DPT DT/T. T. Vaccine :

1. State level—Cold storage Hindustan Anti-biotics Pimpri/Pune
2. District level—Refrigerator D. H. O. Office
3. P. H. C. level—Refrigerators
4. Workers level—Only limited stock for 15 days given at a time. Vaccine is preserved at room temperature for this much period.

A seperate note on cold storage facilities is appended.

Methods used to inform pub ic

1. Convening Gram Sabhas and educating the people.
2. Pamphlets and posters.
3. Mass media like All India Radio and news-papers.
4. Slogan writing on walls.

A. Cold Storage facilities available in the State of Maharashtra

I. Cold storage facilities like deep freeze are available in Bombay, Pune, Nagpur, Aurangabad, Kolhapur and Solapur.

Refrigerators are aveilable in all D. H O. Offices, District Hospitals. Cottage and Rural Hospitals and the Primary Health Centres and few dispenseries.

As would be seen from the flow charts given under sub-heads 11 and 12, the distribution from State level to various district headquarters has to be undertaken by Road TransPort and Railways. This result in transit delay ranging from 3 days to 3 weeks thereby rendering the vaccin potency doubtfnll. To avoid these delays in the transport, following plan is chalked out for vaccin storage and transport within the State :

Vaccine Manufacturing —— Air lift —— 4 Regional Depots at Nagpur, Aurangabad, Pune Kolhapur —— Government vehicle Respective Districts

Peripheral Worker —— through Supervisors —— Primary Health Centre —— Govt. vehicles

Kolhapur is the only place which is till not on the air map. However, very soon it will be and hence it taken as a regional Depot.

II. Apart faom the regional depots to be opened, it will be necessary to hire deep freeze facilities at Kolhapur and Aurangabad since we have Government deep freeze facilities at Pune & Nagpur.

B. Refrigerators at some of the Primary Health Centres are not functioning well or they are out of order. Repairs to the Refrigerators in mofussil areas is a very difficult problem to tackle. It is suggested that four Maintenance-cum-Repair Units for refrigerators should be stationed at the regional depots so as to take immediate necessary repair to keep the refrigerators in good working condition throughout and every-where.

C. In case of sudden breakdown of the refrigerators at D. H. O. Office, a stand-by refrigerator is necessary. Similarly, 25% of the total number of refrigerators in the districts should be also available at district headquarters for immediate replacement.

This requirement for the State would be approximately 50 and the Government of India may negotiate with the UNICEF authorities in this connection. (This has a reference to the minutes of the meeting on M. C. H. held in Delhi on 2nd to 4th November, 1977).

Other requirements would be :

(1) Needles and syringes for BCG (All MPWs will be doing BCG Vaccinations and hence the need).

(2) POL grants for the Government vehicles which will be transporting vaccine from regional depots to districts and from districts to primary health centres

Burma plans attak on Childhood Diseases

Burma has drwn up a programme of immunization against five common diseases of childhood wtih specified targets to be achieved by 1982. The aim is to reduce the incidence of poliomyelitis by 80 per cent, of diphtheria by 75 per cent, of pertusis (Whooping cough) by 65 per cent and of tetanus of the new born by 60 per cent. In Tuberculosis the abjective is to reduce the annual risk of infection by 4o per cent. The programme which will be carried out in stages aims at covering within five years all the eligible person in one-third of the country's population.

The objectives were adopted after detailed study of Burma's health situation as part of a country health programming exercise. Country health programming, an approach strongly recommended by WHO, regards health as a social goal and inter-linked with other soeial goals. It sets a high value on planning health action as an integral part of the overall socio-economic development strategy of a country, and lay stress on the identification ond fullest utilization of locally available resources and manpower.

The study brought to light a tuberculosis infection risk of 17 per 1,000 people annually. Diphtheria was shown to be causing every year 20 cases per 1,000 children 0—4 years old. Whooping cough in the same group accounted for an annual incidence of 40 cases per 1,000. Tetanus infection was estimated to be occuring in 5 per 1,000 live births annually. An ad hoc survey in the Rangoon area gave an indication of paralytic polomyelitis attacking every year 5 per 1,000 children in the 0—4 age group.

The programme as formulated takes in to accout the difficulties likely to be encountered and anticipates all the staffing and supply needs. For instance, one of the major hurdles that an immunization programme must tackle in hot tropical lands is the lack of refrigeration facilities to store and transport vaccines that spoil in the heat. The Burma programme has been so devised that the health assistant in charge of the health centre will draw the vaccine on the first day of every month from the township refrigerator, and carry out the vaccinations in the first week of the month in accordance with a strick schedule of visits to the villages. The schedule will have been worked out in cunsultation with the local midwives and village leaders. Through a similar programme launched last year. Kenya is working towards the goal of reducing by 1984 poliomyelitis by 80 per cent, tetanus by 50 per cent and whooping cough by 25 per cent.

—from *World Health* July, 1977

Methods of Administering Vaccines

Most vaccines are given by inoculation. In developed instruments are cheap and suitabe for all vaccines. Although the jet gun has been extensively used in recent years, it is no longer favoured except in mass compaigns. Where syringes and needles are disinfected by boiling must be through and

syringes and needles must be dry and free from detergent or disinfectant. This is essential to prevent the risk of serum hepatitis transfer. The only vaccine administered by month is live poliomyelitis vaccine Oral BCG is no longer used, and this vaccine is better given intradermally. The simplicity of administering vaccines orally should encourage further research on the use of other oral preparations.

—from—*Who Chronical*
Vol. 31, No. 7, July, 1977

Date of visit	Advice	Next date visit

Was the mother of child vaccinated with Tetanus Tox-oid during pregnancy ? Give particulars

Vaccination	*Date*
B.C.G.	
D.P.T (1st Dose)	
D.P.T. (2nd Dose)	
D.PT. (3rd Dose)	
Smallpox	
Polio (1st Dose)	
Polio (2nd Dose)	
Pholi (3rd Dose)	
Booster Dose	

Immunization Record of Child

Sl. No.————————
Name of the Unit————...————
Date of first visit————————
Name of child————————
Sex————Date of birth/age————
Father's name————————
Address————————

For workers/Team of workers

DAILY IMMUNIZATION RECORD

Name of Unit..... .....
Name of Workers.....

Date :

Batch No.	Aimpules or Vials used	VACCINATION PERFORMANCE	Age (in years) 0—1,	1—3 below 3yrs	3—5 yrs Below 5 yrs	5 & above
		Vaccine				
		Smallpox				
		B.C.G.				
		D.P.T. (1st)				
		D.P.T. (2nd)				
		D.P.T. (3rd)				
		Polie (1st)				

Polio (2nd)
Polio (3rd)
Booster ———
Other ———

Ampoules of vtals of vaccine used:
Batch no of vaccine—
—must also be Entered

This should be bound Register

Individual PHC Monthly report of expanded programme of Immunization

PHC..... Dist.....

Name of Basic Reporting Unit..... ....

Month..... Year.....

A. *Surveillance*

DISEASES	*CASES*	*DEATHS*
1 Diphtheria		
2 Whooping Cough		
3 Tetanus		
4 Measles		
5 Tuberculosis		
6 Poliomyelitis		

VACCINATION PERFORMANCE (*number*)

Smallpox
B.C.G.
D.P.T. (1st)
D.P.T. (2nd)
D.P.T. (3rd)
Polio (1st)
Polio (2nd)
Polio (3rd)
Booster
———
———
Other

C. Condition of refrigerator

Note : PHC worker on the field should send this information to MO/PHC. Watch for deputation of cases and special investigation be done whether any overlapping and over reporting in respect of Immunization against TB & Polio.

REGISTER OF IMMUNIZATION

Serial No.		Name of Child	Father's Name	Month of Birth years Approxi	House No.	Municipal House No.	Village	Date of Vaccination
Card No.	Index No.							B.C.G. Smallpox D.P.T. (I) D.P.T. (II) D.P.T. (III) Booster

—This Register shall be available at PHC Sub Centre Level.
—Individual Village were Register must be *kept*.
—Similar Register at all places with Village wise Index.

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POTENCY OF FIELD SAMPLES OF ORAL POLIOVIRUS VACCINE

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The transport and storage facilities and the potency of oral poliovirus vaccines currently administered in 108 centres in India were investigated. Storage and distribution practices in many of the centres were far from ideal. There was no significant loss of potency in the vaccine samples collected from a few centres, while samples from other centres showed a 60-90% loss of virus particles per dose. A national monitoring system has since been established to check the potency of every batch of oral poliovirus vaccine imported and to streamline the transport, storage, and administration of the vaccine. Constant vigilance as regards the quality of vaccines should ensure the success of any poliomyelitis immunization campaign.

The detection of a measurable circulating serum antibody is a valuable index of the effect of a programme of immunization with oral poliovirus vaccine. Cabasso et al. (3) demonstrated circulating antibodies against all three polioviruses of 90% of vaccinated children one month after they had received two doses of trivalent vaccine. Live vaccine, in countries with a warm climate, is known not to produce seroconversion in such a high proportion of children (5, 8). Interference from other enteroviruses present in the gut, the presence of antibody in breast milk, and the development of cellular resistance owing to previous exposure to natural polioviruses and/or perhaps to related viruses or protein deficiency, have all been mentioned as factors responsible for low seroconversion rates (4). Montenfiore (7) reported that, when reasonable care was taken at all stages, low seroconversion rates could not be attributed only to faulty administration, while Brito Bastos et al. (2) emphasized the need for evaluating vaccine potency in terms of virus particles per dose.

To determine whether the potency of the vaccine played a role in the low seroconversion rates found in a country with a warm climate—India—vaccine samples were obtained from importers, distributors and immunization centres in various parts of the country. The potency of the individual samples was determined in terms of virus particles per dose so as to calculate any loss of vaccine potency.

MATERIALS AND METHODS

Collection of vaccine samples

Vaccine samples was obtained from Delhi, Jaipur, Kanpur, Bhopal, Calcutta, Madras, Bombay, Jagadhari, Mathura, Meerut, Ferozepur, Ambala, Kasganj, and Chandigarh. As far as possible, amounts representing 10—20 doses of a particular vaccine lot were collected aseptically in a sterile universal container. The labelled containers were stored on solid carbon dioxide and shipped to the laboratory with the least possible delay. The samples were stored in the laboratory at—65°C to—70°C in a deep-freeze. Whenever a sample was obtained from a distributor or from an immunization centre, the supplier was asked to answer the questions indicated in Table 1.

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The storage facilities were inspected and, as far as was practicable, suggestions were made for remedying any defects.

Determination of virus content of vaccine samples

The vaccine samples were titrated for the total live virus content in primary rhesus monkey kidney cell cultures. The kidneys, from adult monkeys that had been kept in quarantine for different periods, were trypsinized overnight at 4°C (1). The culture medium was Hanks balanced salt solution containing 0.5% lactalbumin hydrolysate (Difco), 5% goat serum (obtained from the Delhi slaughter house), and antibiotics. The cells were washed with phosphate-buffered saline (pH 7.3) before being transferred to the maintenance medium (tissueculture medium TC 199[a] with 0.2% bovine albumin and antibiotics).

Table 1. Information to be obtained during the collection of a vaccine sample

From all sources	From distributors of vaccine	From immunization centres
Whether the vaccine was stored in a deep-freeze or refrigerator	Despatch arrangements from the Premises of the importers	Permissible cycles of frezing and thawing
Availability of alternative storage arrangements in the event of a power break-down	Despatch or distribution to the immunization centre	Withdrawal of the vaccine from vials
Maintenance and care of the freezing equipment		Use of diluents, such as water of syrup, before administration of the vaccine
		Whether breast-feeding was considered to be a contra-indication to the administration of the vaccine
		Any unusual practice or recommendation regarding poliomyelitis vaccination

Serial 10-fold dilutions of different samples were made in the maintenance medium and 0.2-ml volumes of the appropriate dilutions—usually 10^{-5}, 10^{-6}, and 10^{-7}—were inoculated into 10 culture tubes and incubated at 35± 1°C in a roller drum incubator. The final readings were made on the seventh day and the virus content of the vaccine was determined in terms of $TCID_{50}$ per ml by means of the Reed & Muench (*12*) formula. As a check on the sensitivity of the kidney cell cultures, a reference virus was titrated simultaneously with the vaccine samples.

Methods of computing loss of vaccine potency and of determinining the significance of differences in potency are described in the Annex.

results

Storage and distribution

In 21 of the 108 centres visited, vaccines were stored in a deep-freeze at —20°C; in 68 centres, in the freezing chamber of the refrigerator; and in 26 centres, in the main storage compartment of the refrigerator. In one centre, the vaccine was kept at room temperature, while in another it was stored inside an earthen pitcher. Only 8 centres had installed a stand-by generator to prevent any interruption in power supply to the deep-freeze or refrigerator containing the poliovaccine. Maintenance of the deep-freeze or refrigerator appeared to be satisfactory in only 42 of the centres visited.

In none of the centres was there any awareness of the effects of cycles of freezing and thawing on the vaccines. Sixty-nine of the samples were from vials from which the rubber stoppers had been removed

[a] Difco Laboratories, Detroit, MI 18232, USA

before the contents were used. However 42 centres reported that the rubber stoppers were never removed and that the contents were removed with a sterile syringe and needle. At 62 centres the vaccine was delivered direct into the recipient's mouth by means of a syringe or plastic pipette, while 33 centres employed plastic or metal spoons. In only 2 centres was the vaccine diluted in 5-10 ml of water before administration; disinfectant, soap, or potassium permanganate was used for washing the spoons in a few centres. In one centre the desired amount of vaccine was injected into a cube of desiccated semi-porous sugar, which was fed to the person to be vaccinated. In only 38 centres were mothers instructed to avoid breast-feeding for a time after vaccination. Food of any kind was prohibited during the ½-2 hour post-vaccination period in 23 centres.

Loss of potency during storage

Of the 191 samples tested, 113 did not show any reduction in titre (Table 2). There was a 0.1-0.3-log reduction in the titre of the individual dose in 22 samples. Statistical analysis with the Pizzi formula (*10*) did not always reveal a significant loss of potency in such samples, although the loss may well have been biologically significant. The centres from which these 22 samples were obtained were informed that the loss of potency in their sampies was marginal. In 56 samples (30% of the total), the titre of the individual dose showed a reduction of at least 0.4 log. This loss was always found to be statistically significant. The centres that supplied samples of such low-titre vaccine were informed of the results immediately and advised to destroy the remaining lots of the vaccine from which the representative samples had been drawn. In 6 centres, the sample drawn fram the stored vaccine was found to be satisfactory, while the vaccine that was actually given to children showed a significant reduction in potency.

Table 2. Result of potency testing of 191 vaccine samples

Manufacturer or supplier of the vaccine	Samples tested	Samples showing no loss of potency	Samples showing loss of potency (in log scale and percentages)			
			20-50% or 0.1-0.3 log	60-90% or 0.4-1.0 log	92-99% or 1.1-2.0 log	more than 99% > 2.0 log
Institute of poliomyelitis, Moscow (liquid vaccine)	154	103	16	28	7	—
Institute of poliomyelitis, Moscow (dragees)	4		—	4	—	—
Lederle Laboratories, Pearl River, NY	3	—	1	1	1	—
Institute of Immunology and Virology, Belgrade	2	—	—	—	—	2
Haffkine Institute, Bombay*	27	9	5	9	3	1
Pasteur Institute, Coonoor	1	1	—	—	—	—
Total	191	113	22	42	11	3

*Vaccine imported in bulk was bottled at this Institute.

Remedial measures

In the initial phase of this study it was found that neither the main importers nor the regional or peripheral distributors took care to despatch the vaccine at sub-zero temperatures. They were using wet ice with or without insulating material. The peripheral immunization centres were obtaining their supplies in vaccum flasks with or without ice. When the preliminary results of the survey were known, it was made obligatory for the main importers to distribute all vaccine supplies on solid carbon dioxide, and this has since been adopted as standard practice in India. It is recommended by the Indian national drug control authorities that, once the vaccine has reached the regional or peripheral distributors, it should be stored only in a deep-freeze at —20°C. Supplies are subsequently distributed to the field on solid carbon dioxide or in a freezing mixture, so that the vaccine is transported at sub-zero temperatures.

A constant check is now being maintained on all imported batches of poliovirus vaccines. Samples are taken at the port of entry and are flown to the testing loboratory on solid carbon dioxide, thus ensuring that only fully potent veccines are released from the importer's premises. A periodic check is also made at the premises of the regional distributors located in various parts of the country.

DISCUSSION

The incidence of poliomyelitis is increasing in many countries (*4*) and the low seroconversion rates that have been reported indicate low efficacy of oral poliovirus vaccine, In addition to interference from other enteroviruses. other factors—antibody in breast milk, protein deficiency, celluler resistance to poliovirus or related viruses, and even inhibitors in the saliva and in throat swabs from antibody-free children—heve been incriminated (*13*) Surprisingly, no systematic work appears to have been done to assess the potency of the vaccines being administered in doveloping countries, although Brito Bastos et al. (*2*) have stressed the need to test vaccine potency in terms of the number of virus particles present per dose,

The poliovirus titre for each filing lot should be determined routinely before the vaccine (14) is distributed. However, the fact that any particular lot is fully potent before distribution is no sugarantee that every dose from that lot will be fully potent when it is administered, and this is crucial to the success of any vaccination campaign.

Storage in an opened or loosely capped vial increases the pH and together with other factors may accelerate sigificanty the loss of vaccine titre (6). The storage conditions in a refrigerator or deep-freeze must also be checked regularly and care is required to ensure that the vaccines are used bsfore the expiry date. Vaccines should not be exposed to light or to ambient temperatures for long periods before administration.

When cases of poliomyelitis occur after vaccination, a serious attempt should be made to ascertain the potency of the vaccine that was administered. There appears to be ample justification for reexmining the criteria for a causel assoeiation with vaccination (*9*), Undoubtedly, the potency of the vaccine should be the most important factor in this regard in areas where wild viruses are endemic

This study has emphasised the need for the national control authorities to exercise control over all batches of vaccines used in the country. Vaccine samples for the testing of potency should be obtained regularly at the port of entry and from indigenous manufacture, wholesale and regional distributors, local storage depots, and vaccination centres, Dealers, health administrators and parents should be made aware of their respective roles. Frequent surprise inpections at immunisation centres are also valuble.

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RESUME

Activite D'e chantillons De Vaccin Antipoliomyeltique (buccal) Preleves) Preleves sur Le Terrain

Afin de determiner dans quelle mesure Pactivite duvaccin rntipoliomylitiqee (buccal) est le facteur responsable de le mediocre efficacite de ce vaccin dans les climats chauds, on a preleve des echantillons a partir de lots de vaccins utilises sur le terrain. et mesure l'activitie de ees echantillons. On a inrpecte un total de 108 centres situes dans diverses parties de l' Inde afin d'evaluer les mayens de transport et de stockage du vaccin dont ils disposaient, et l'on y a recuelli des echantillons de vaccin. Il est apparu que les prariques de stockage et de distribution de plusieurs centres etaient loine d'etre ideales, Les echantillons de vaccin provenant d'un petit nombre de centres ne presentaient aucune perte d'activite notable, alors que dans ceux d'autres centres, il y avait une baisse de 60— a 99—du nombre de particules virals presentes dans les doses individuells.

Dans les cas ou une poliomyelite servient apres vaccination, il faut s'efforcer de verifier l'activite du vaccin qui avait ete administre. Il semble bien qu'a cet egard Pactivite du vaccin soit le facteur le plus important dans des regions ou des virus sauvages sont endemiques. Un controle constant de la qualite du vaccin devrait assurer le succes do toute compagne d'immunisation contre la poliomyelite, meme dans les climats chauds.

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ANNEX

Computation of loss of Vaccine Potency and test of significance References

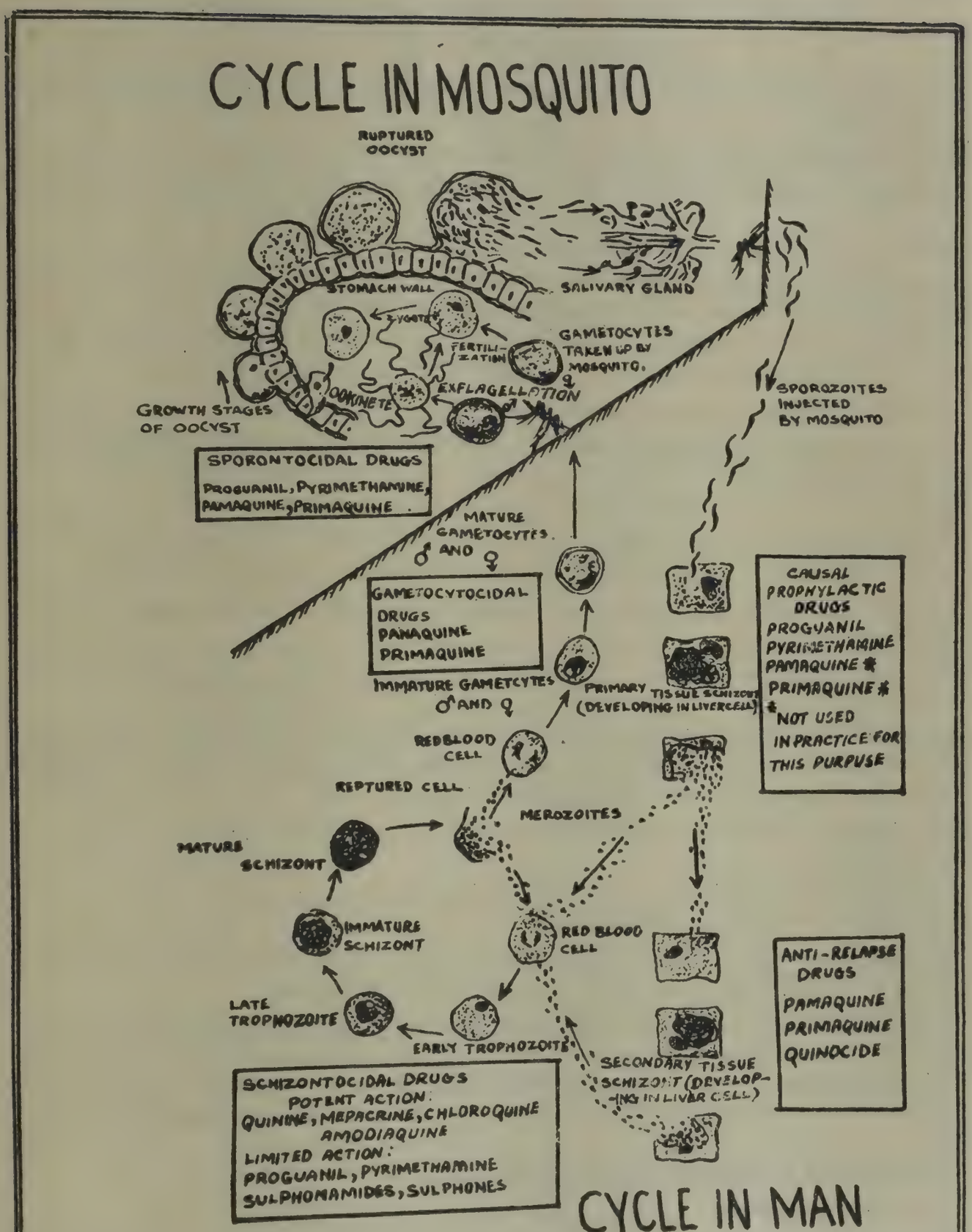
The virus content of each dose is calculated from from its $TCID_{50}$/ml value on the basis of the volume recommended by the manufacturer for each dose. Since the virus content of a sample of trivalent vaccine containing $10^{5.7}$ or $10^{6.0}$ of type 1, $10^{5.0}$ of type 2, and $10^{5.5}$ of type 3 may be expected to be $10^{6.0-6.2}$ $TCID_{50}$, the exact loss of potency is computed on the assumption that a sample with a virus content of 10^6 has a potency of 100%. Thus two samples with a total virus content of 10^5 and 10^4 may be considered to have lost 90% and 99 % of their potency, respectively.

The standard error of the individual titre is calculated with the formula developed by Pizzi (10), i.e., (SE) standard error of $ID_{50} = \sqrt{(0.79\ hR)/n}$ where 0.79 is a constant, h is the log of the Dilution factor, R is the intervai on the log scale between the cumulative 25% and 75% end-points, and n is the number of tubes per dilution.

To test the significance of the difference between any two virus titres, the following calculation is made.

$$T_1 - T_2 / \sqrt{Se_1^2 + Se_2^2}$$

where T_1 is the first titre, T_2 is the second titre, Se_1 is the standard error of the first titre, and Se_2 is the standard error of second titre). If this calculation yields a value of 2 or more, the difference between virus titres, is regarded as statistically significant with 95% limits of confidence.


CYCLE IN MOSQUITO
RUPTURED OOCYST
STOMACH WALL
SALIVARY GLAND
ZYGOTE
FERTILI-ZATION
GAMETOCYTES TAKEN UP BY MOSQUITO.
EXFLAGELLATION
OOKINETE
GROWTH STAGES OF OOCYST
SPOROZOITES INJECTED BY MOSQUITO
SPORONTOCIDAL DRUGS
PROGUANIL, PYRIMETHAMINE, PAMAQUINE, PRIMAQUINE
MATURE GAMETOCYTES ♂ AND ♀
GAMETOCYTOCIDAL DRUGS
PANAQUINE
PRIMAQUINE
IMMATURE GAMETCYTES ♂ AND ♀
PRIMARY TISSUE SCHIZONT (DEVELOPING IN LIVER CELL)
CAUSAL PROPHYLACTIC DRUGS
PROGUANIL
PYRIMETHAMINE
PAMAQUINE *
PRIMAQUINE *
* NOT USED IN PRACTICE FOR THIS PURPUSE
REDBLOOD CELL
REPTURED CELL
MEROZOITES
MATURE SCHIZONT
IMMATURE SCHIZONT
RED BLOOD CELL
LATE TROPHOZOITE
EARLY TROPHOZOITE
ANTI-RELAPSE DRUGS
PAMAQUINE
PRIMAQUINE
QUINOCIDE
SECONDARY TISSUE SCHIZONT (DEVELOPING IN LIVER CELL)
SCHIZONTOCIDAL DRUGS
POTENT ACTION:
QUININE, MEPACRINE, CHLOROQUINE AMODIAQUINE
LIMITED ACTION:
PROGUANIL, PYRIMETHAMINE
SULPHONAMIDES, SULPHONES
CYCLE IN MAN

NATIONAL INSTITUTE OF COMMUNICABLE DISEASES : CHEMOTHERAPY OF MĀLARIA

Terminology used in the chemotherapy of malaria—Blood schizontocide A drug which acts on asexual parasites in the blood.

Tissue schizontocide a drug which acts on asexual parasites in the tissues.

(a) Primary tissue schizontocide A drug which acts on preerythrocytic (Primary exoerythrocytic) forms .

Gametocytocide A drug whic destroy the sexual forms of malaria parasites.

Sporanotacide A drug which, when given to the malaria-infected verterbrate host, prevents or interrupts the development of the parasite in mosquitoes feeding on that host.

Prophylaxis—casual Complete prevention of erythrocytic infection by administration of drugs that destroy either the sporozoites or the primary tissue forms of the malaria parasite.

Prophylaxis—clinical Synomym of suprresive treatment.

Treatment—suppressive Treatment aimed at preventing or eliminating clinical symptoms and/or parasitaemia by early destruction of erythrocytic parasites. It does not necessarily prevent or eliminate the infection, and overt malaria may develop after drug withdrawl

Treatment—radical Treatment adequate to achieve radical cure, In vivax, malariae and ovale infections, this implies the use of drugs which destroy the secondary tissue stages of the parasite.

Treatment—anti-relapse Treatment aimed at the prevention of relapses particurlarly long-term relapses.

Cure—ctinical Relief of symptoms of malaria attack without complete elimination of the infection.

Cure—radical Complete elimination of the malaria parasite from the body so that relapses cannot occur. Radical cnre may be brought about by natural means in the absence of specific medication (natural or spontaneous cure), by redical treatment or by suppressive cure.

Cure—Suppressive Complete elimination of the parasite from the body by means of continuous Suppressive treatment

Recrudescence Renewed manifestation of infection (short-term relapse) belived due to survival of erythrocytic form Not to be confused with recurrence.

Recurrence Renewed manifestation of infection (long term relapse) believed due to reinfection of erythrocytes from exoerythrocytic forms. Not to be confused with recrudesence.

Relpase Renewed manifestation (of clinical symptoms) and/or parasitaemia of malarial infection separate from previous manifestations of the same infection by an interval greater than those due to the normal periodtcity of the paroxysms. The qualifications "short-term" and "long-term" may be used to designate relapses following the primary attack after intervals of less than two or more than six months respectively.

I. The prevention and treatment of clinical manifestations

A. Routine Trnatment

Preventiion and treatment of the over material attack is obtained with anti-malarials that are active against the asexual erythrocytic forms of the parasite. These are called *Schizontoridal drugs*

Some of these drugs exhibit, besides a relatively week schizonotocidal action, an action against pre-erythrocytic stages, which render them excellent for prophylaxis although less effective for treatment of the overt attack.

1. 4—Aminoquinolines

The most common representative of this group are ;

1.1—Chloroquine—(Syn : aralen, avlochor, nivaquine, resochin)

action—Strong action on asexal erythrocytic stages of all human malaria parasite species by inhibiting respiratory enzymes of the parasites.

Dosage—Since some tablets contain the drug in the form of the diphosphate (containing 60% chloroquine base), other in the form of the sulphate (containing 75% of the base),etc., one shouid always referto the amount of ***chloroquine base***.

For prophylaxis (once weekly)

infants	37.3 mgm	chloroquine base
Pre-school children	75 mgm	,, ,,
School children	150 mgm	,, ,,
adolescents/adults	300 mgm	,, ,,

For treatment

(a) in semi-immune subjects (single dose treatment)

infants	75 mgm chloroquine base
Children :	
1--2 years	150 mgm ,, ,,
3—5 years	300 mgm ,, ,,
School children	450 mgm ,, ,,
Adolescents	600 mgm ,, ,,

*According to body weight, approximately 10 mgm chloroquine base per kgm body weight

(b) In non-immune subjects

The single dose treatment may give temporary relief of complaints and sometimes temporary disappearance of malaria parasities from the peripheral bloodstrem, but should be eonsidered generally insufficient for treatment of the overt attack. For non-immune the treatment is therefore prolonged as

	Initial dose	*2nd day*	*3rd day*	
infants	75	75	37.5	mgm base
children ;				
1—4 years	150	150	75	,, ,,
5—8 years	300	300	150	,, ,,
9—14 years	450	450	225	,, ,,
Adults	600	600	300	,, ,,

The schedule may be modified as 600 mg at once followed by 300 mg. at 6, 24 and 48 hours after the first dose or 600 mg. 450 mg, on 1st, 2nd 3rd day.

1.2 **Amodiaquine** (Syn : camoquin, flavoquine)

Action : As chloroquine (see below)

Dosage : **For prophylaxis** (Once weekly)

infants	50 mgm	amodiaquine base
Pre-rchool children	100 mgm	,, ,,
school children	200 mgm	,, ,,
adolescents adults	400 mgm	,, ,,

For treatment

The dosage schemes given above for chloroquine may be followed. As tablets may contain 200 mgm base instead of 150 mgm base, the following schedules would be more convenient and equally good.

(a) **In semi-immune subjects** (single dose treatment)

infants	100 mgm amodiaquine base
children	
1—2 years	200 mgm ,, ,,
3—5 years	300 mgm ,, ,,
school children	400 mgm ,, ,,
adolescent/adults	400—600 mgm ,, ,,

(b) in non-immune subjects

	1st day	2nd day	3rd day
infants	100	50	100 mgm base
children :			
1—2 years	200	100	100 ,, ,,
3—5 years	300	300	300 ,, ,,
school children	400	300	300 ,, ,,
adolescents/adults	600	400	400 ,, ,,

A prophylactic regimen with one of these drugs may be commenced immediately before entering a malarious area, but should be continued for one month after leavtng to secure suppression of a *P. falciparum infection* (suppressive cure), Relapses of *P viuax* (*P. malaria* and *P ovale*) may occur anytime afterwards as these drugs do not act on tissue phases of the parasites. To prevent relapses, the prophylaxis should be concluded with a radical treatment (radical cure) upon departure from the malarious area.

2 **Pyrimethamine** (Syn : daraprim, erbaprelina, malocide, etc.)

Action : The drug exhibits a less powerful schizontocial action against malaria parasites. It acts morever on pre-erythrocytic forms of *P falciparum*. Its sprontocidal acticity makes the gametocytes harmless for transmission from 3 to 4 hours after ingestion for some weeks.

Dosaga : For prophylaxis (once weekly) The drug is tasteless

Children :	
0—5 years	6.25 mgm pyrimethamine base
6—12 years	12.5 ,, ,, ,,
Adolescents/adults	25 ,, ,, ,,

For treatment—Not recommended

3. **Proguanil** (Syn : paludrine, palusil, chlorguandie, etc.)

Action : As of pyrimethamine (2 above)

Dosage : For prophylaxis (Once daily)

Children :—

0-5 years	25 mgm proguanil monohydrochloride
6-12 ,,	50 mgm ,, ,,
Adolescents/adults	100 mgm ,, ,,

Deviations of this schedule are known. Neither the reduced adult dose of 50 mgm once weekly, nor the increased dose (up to 200 mgm for adults daily) generally recommendeu, as these may induce drug-resistance.

The drug has a bitter taste.

For treatment—Not recommended

In several parts of the world malaria parasites (mainly *P. falciparum* and *P. vivax* have shown a resistance to pyrimethamine, proguanil and related drugs as Chlorprogunil (laqudrine). In these areas one will have to resort to otoer drugs as prophylactics.

Prophylaxis with any of these drugs should be commenced immediately before entering the malarious area, On leaving the malarious area, prophylaxis should be continued for at least two weeks, in order to ensure a suppressive cure of a *P. falciparum* infection which may have been contracted during the last days of the stay in the malarious area. As the effect of these drugs on the pre-erythrocytic forms of *P. vivax* is weak, one should count on the possibility of clinical manifestation. In order to avoid this the prophylactic regiman should be concluded with a radical treatment (radical cure) of *P. vivax* which may be instituted immediately upon departure from the malarious area.

4. **Quinine**—(as sulphate or dihydrochloride)

Action.—**As 4—aminoquinolines**

Not generally recommended because of length of course and some side-effects. The drug remains of value for emergency treatment (see below) and regained interest recently in the treatment of *falciparum* malaria, resistant to most synthetic anti-malarials, notably to the 4-aminoquinolines (see below)

Dosage :—**For prophylaxis**

Adult dose :—650 mgm daily—Not recommended.

For treatment

a in semi-immune subiecrs—(daily for 2-5 days in divided doses)

infants 10 mgm quine for each month of age
children 100 mgm quine for each year of age
adolescents 1200—
adults 1500 mgm quine

(b) in non-immune subject (daily for 7 days in divided doses)

The same schedule as for semi-immune subject. Some authors keep 30 grains (1950 mgm) as the daily adult dose.

5. **Mepacrine**—As hydrochloride (Syn ; atebrine, quinacrine, etc).

Action—As 4—aminoquinolines

Not recommended when alternat:ve schizontocidal drugs are available.

Dosage:—**For prophdlaxis**

Adult dose :—100 mgm daily.

For treatment

(a) **in semi-immune scbects**—(single dose treatment}
Adult dose : 300—500 mgm hydrochloride

(b) **in non-immdne subjects**
Adult dose : 300 mgm (three times on first day)
300 mgm (twice on second day)
100 mgm (three times on third to seven days)

6. **Primaquine**—(related drugs : pamaquine, quinocide)

Action : A pefinite action on pre-erythrocytic forms of at least *P. falciparum* and *P. vivax* however, at doses too high to permit the use of this drug for the purpose of prophylaxis.

Dosage : The prophylactic regimen in these instances consists of a weekly dose of 300 mg of 4-aminoquinoline with 45 mgm primaquine base (adult dose)

B. Emergency treatment—In the treatment of peticious forms of malaria (nearly all P falciparum) oral administration of drugs may be not feasible, and anti-malarials will have to be given parenterally Depending on the exact clinical situation parenteral. treatment is given either intramuscularly or intravenously. Wheras the former route may be selected in cases of simple vomiting, in some forms of cerebral malaria, or in cases where the emergency is based on the parasitological fiindings rather than on alarming clinical manifestations, in other cases of cerebral malaria, or in cases where the emergency is based on the parasitological findings rather than on alarming clinical manifestations, in other cases of cerebral malaria, in prolonged vomiting or shock, the intravenous route may be preferred. especially.
as in intravenuas route may be preferred, ar blood transmission may be necessary in these cases as well.

In all instances the parenteral treatment. should be substituted by oral treatment as soon as the patient is ablt to swallow the drugs and reyain them and the danger is over.

1. Intramascular Injection

(a) Chloroquine (as hydrochloride)

Dosage : At most 5 mgm chloroquine base per kilogramme body weight (commonly 10cc of 5% solution of salt, which is equivalent to 300—400 mgm chloroquine base, for an adult). This dose may be repeated after six hours, if necessary and again after twelve hours, if necessary; the total adult dose should not exceed 900 mgm chloroquine base, spread over 24 hours.

(b) Quinine

Dosage : Not recommended because of possible muscular necrosis and abscess formation at the site of the injection. When no other treatment is available quinine hydrochloride, quinine urethane, or quining—antipprin in an adult dose not exceeding 1000 mgm may be given to be repeated after 24 hours, if necessary.

2.Intravenous in)ection

(a) Qunine

Dosage : When given in a single dose, for adults at most 650 mgm quinine hydrochloride dissolved in atleast 20cc physiological saline, injucted at a speed not exeeding 1cclperminute.

It is far safer to a he drug in 500cc physiological saline, glucose salinel plasmar blood and give it as a continuous intravenious drip.

Dose for adults : 650 mgm quinine hydrochloride not exceeding 2000 mgm in 24 hrs.

(b) Chlorioquinc

Dosage *:* The drug is best given by intravenous infusion in 500cc of saline, etc., not exceeding 400 mgm chloroquine base in 24 hrs.

3. Non-Specific cerapy

Additional medication in the treatment of pernicious forms of malaria is important.

An infusion are blood tronsfusion is indicated in severe dehydration and anaemia; the addition of sedatives (Barbiturates) may be indicated in case of convulsions or restlessness ; other special therapy as and when required.

II The preventi on of relalapses : Radical Cure

Any of the more powerfull schizontocidal drugs, when given in appropriate doses, will effect radical cure in the *P. falsiparum* malaria by climinating the erythrocytic asexual forms.

In *P. Vivax, P ovale* and *P malariae* such a treatment may not result in rrdical cure, as seoondary tissue forms remain un aflacted schizontocides, and a relapse, originating in these lrver forms, may occur. To obtain a *radical cure* in infections with any of there three parasite speies, a drug eliminating the secondary tissue forms and therby preventing relpases will have to be added to the schizontocidal drug *anti relapse* drug.

It is to be noted that in situations where the chance of acquiring a reinfection is as great as or greater than that of suffering a relapse, as in unabated hyperendemic malaria the use of anti-relapse drugs is rather redundant.

1. Aminoquinolines

A number of representatives of this group hav been used for this purpose in the past. The most effective and least toxic drug presently avilable is :

Primaquine (Syn: primaquine) related drug : quinocide (USSR) equally well, same action, dosage and toxicity

Action : Under ordinary circumstances, Prince a quine close of radical cure in *vivax* infection has been obtaind with recommended doses. It also has gamtocytocidal action.

Dosage ; Since the relapsing tendency (potential) of *P- vivax* has been shown to differ widely in the various strans of this species, the recommended dosage of primquine in radical treatment varies aecardingly.

In the trentment of overt malaria, primaquine lacking itself any schizontocidal actlon, will have to be combined with a schizontocidal drug in usual amounts. This combinatıon costitutes radical cure in P. vivax and P. malariae.

A number of regiments can be oistinguished.

(a) standard scheme (daily) for 14 days)

Infants	Nil
Children : 1—4 years	2.5 mgm primaquine base
5—8 years	5 mgm ,, ,,
9—15	10 mgm ,, ,,
adults	I5 mgm ,, ,,

(b) **Reduced Scheme**

The same as above, but given for only 5—7 days, where it has been shown that the proportion of 'break-throughs' is not substantially higher than with the standard scheme. This is dependent on the vivax strains.

(c) **Improved scheme** (weekly for 8 weeks)

	Chloroquine base	**+ primaquine base**
	–	–
infants : 0—5 months	75 mgm	7.5 mgm
6—11 ,,	150 mgm	15 mgm
children : 1—4 years	150 mgm	22.5 mgm
5—10 ,,	300 mgm	30-45 mgm
adoleescent/adults		

In chesson strain *P. vivax*, notorious for its powerful relapsing tendency, with 30/o "braak-throughs" a weekly scheme appears superior to any other scheme, while less toxic. The effect can be further improved by prolonging the treatment, e.g., 12 weeks, weekly 45 mgm primaquine base (adult dose) .

III The prevention of Transmisson

To prevent further spread of malaria from a parasite carrier (patient) a drug is required which acts against gametocytes either by destroying them gametocytocidal drugs, or by inhibiting their further development inside the mosquito's body. This latter effect, sometimes referred to as a sterilizing action, is exhibited by *sporonatocidal drugs.*

Gametocytes, of *P. vivax, P. ovale* and *P. malariae* are destroyed by common schizontocidal drugs, and therfore, do not require any special attention,

Gametocytes of *P falciparum*, however, are not destroyed by schizontocidal drugs, nor inhibited in their further development in the vector. Although the production of new gametocytes is blocked by schizontocides through their action on merozoites, existing gametocytes remain unaffected and on the average, remain infactive for three weeks.

Whereas, in situtations of high malria endemicity the prevention of transmission through the addition of gametocytocidal/sporontocidal drug in the routine treatment of *P. falciparum* malaria, may be redundant, in areas of low endemicity, and particularly in areas where a malaria eradication programme is underway, it may be of utmost importance to render malaria patients non-infective to mosquitoes as early as possible,

Gametocytocidel and sporontocidal drugs against P. falciparum

Primaquine

Action : Only drug known to destrory gametocytes of *P falciparum*. It takes, however, 3-5 days before this effect is achieved, The drug has morever a sporontocidal action noticeable within 1-2 days.

Dosage : **Single dose treatment.**

infants :	0—5 months				
	6—11 „	7.5	mgm primaquine base		
children :	1—5 years	15	„	„	„
	5—10 „	22.5	„	„	„
adolescents/adults		30-45	„	„	„

(b) **three days treatment (daily) :—**

infants					
children :	1—2 years	3.7	mgm primaquine base		
	3—5 „	5	„	„	„
	6—11 „	7.5	„	„	„
adolescents/adults		15	„	„	„

Pyrimethamine

Action : Fastest sporontocidal action. noticeable within 24 hours. The action may last for about three weeks, i. e. nearly as long as the average life-span of the gametocytes of ***P. falciparum***.

Dosage : **Singie dose treatment**

infants :	0—5 months	6.25	mgm pyrimethamine base	
	6—11 „	12.5	„	„
Pre-school chiidren		25 „	„	„
School children		22—37.5 mgm	„	„
adole scents/adults		50 „	„	„

Chloroguanil and **proguanil**

These drugs have in a single does of 20 mgm chloroproguanil or 100 mgm proguanil (adult dose a similar effect, which lasts, however, only one week and a few days, respectively,

Prophylaxis and curativetreatment ef drug-resistant P. falciparum

Prophylaxis of drug-resistant P. falciparum

(after Dr. David F. Clyde, University of Maryland. Baltimore)

A decade ago, the chemoprophylaxis of malaria was routinely and effectively assured on an individual or communal basis by the ingestion at intervals of one week of chloroquine, amodiaquine or pyrimethamine, or daily of chloroquide (Proguanil). In much of South America and Asia these regimens are no longer protective against *P. falciparum* and indeed at the present time we are in a difficult position

when asked to make a suitable recommendation. Although the addition of primaquine to the weekly dose of chloraquine improved its prophylactic effectiveness in some areas of resistance, up to 50 per cent of falciparum infection break through in carefully supervised test systems, and the combination is not always tolerated comfortably.

For practical purposes, only the sulfones and sulfonamides are available to us at the present time as reasonably assured suppressives of multi-drugs resistant *P. falciparum*. This group of drugs given by mouth has the advantage of effective suppression of almost all falciparum infections whether resistant to other antimalarials or not. It produces a minimum side effects either of a minor nature, such as gastic intolerance, or of major significance : following the prophylactic use of DDS, cases of agranulocytosis or of sevrer henolytic anemia in C6PD—deficent hen aiso receiving primaquine are extremely rare, as are cases of stevens-Johnson syndrome following sulfonamide treatment. Given intramuscularly, the repositiory sulfone DADDS produces local tissue reactions generally of a minor irritant nature in up to 30 per cent of cases. However, these drugs do not suppress *P. vivex*, for which purpose other anti-mala arils must also be used.

The occasional instances of *P. falciparum* break-through by serveral workers in the field no tably Verdrager (1969). have been attributed to the development of resistance by the parasite to the sulfones and sulfonamides. Most of those workers, however, express the reservation that a contributing cause may be drug failure rather than resistance, the drugs being inactivated rapidly by some mechanism such as protein binding, an explanation more consistent with recent studies at my centre. There is one other disadvantage to which importance is attached : the risk of inducing resistance in certain pathogenic bacteria. The repetitive use over long periods of time of relatively small doses of sulfonamides in populations among which there are always some carriers of the meningococcus is regarded by many anthorities as potentially so hazardous as to constitute an absolute containdication.

Two sulfones, DDS (dapsone) given by mouth each day and DADDS (diactyle—DDS) by intramuscular injection at intervals of serveral months, have been used extensively in field operations while a third. DFD (diformyl—DDS), given by mouth at intervals of one week, continues to be tested in volunteers and being still experimental, will not be discussed here. In the field in areas of high transmission, DDS has been administered orally each day to non-immune adults in a dosage of 25 mg, either with chloroquanide (proguanil) daily or with pyrimethamine or chloroquine and primaquine weekly : the latter regimen reduced malaria incidence the fold compared to the use of chloroquine and primaquine without DDS (Joy et al., 1969). DADDS has been given intramuscularly with cycloguanil in several countries : an example is the use of the combination in a median dose of 7.5—7.9 mg/kg at 4 month intervals in children in Amapa, Brazil (Gusmao and Juaroz, 1970), falciparum infections resistant to 4-aminoquinolines being suppressed almost entirely for 3 months following each injection.

The apprehension expressed concering the development of resistance in pathogenic bacteria has markediy inhibited field use of the sulfinamides for the prophylaxis of malaria. The combination of sulfadoxine (sulformethoxine) 500 mg and pyrimethamine 25 mg (adult dose), given at weekly intervals, has proved successful in protecting non-immunes in an area of transmission of chloroquine resistant and pyrime thamine resistant *P. falciparum* (Ebisawa et al., 1970), and similarly good results have been obtalnod against chloroquine sensitive strains.

Summary

(Based on experimental infections with Southeast Asian strains in USA.

a. **Chloroquine (300 mg) + Primaquine** (45 mg) protects against part of the resistant infections in Viet Nam and Malaysia (apart from protection against sensitive strains, *P. vivax*, *P. malariae* and *P. ovale*.

b. Addittion of sulfalene (200-250 mg) weekly	Protects against all Viet Nam strains.
c. Addition of DFD (10 —800 mg) weekly	Almost as good as (b) but a few 'break throughs'.
d. Addition of DDS (25 mg daily	As c), protective in most of Southeast Asia.
e. Proguanil (200 mg) daily	Protective in Malaysia, but failed in parts of Viet Nam.
f. Pyrimethamine (25 mg) weekly	Protects against some Viet Nam strains, fails agaiust others and in Thailand and most of Malaysia.

Similarly in instances of recudescences, despite a fortnightly treatment with quinine, it may be required to provide for a fully curativetreatment. For this the following outline is given :

Curative treatment of drug-resistant *P. falciparum* (after Dr. David F. Clyde, University of Maryland, Baltimore).

In the earely days of emergence of chloroquine resistant falciparum malaria, it was often sufficient to increase the dose of chloroquine particularly when treating semi- immune patients (for example, see the by Gracia-Martin, 1963). Even now the related 4–amino quinoline amodiaquine may be effective in some cases responding poorly to chluroquine- However, use of any members of this group of drugs is no longer advisable in acute infections in non immunes, being safer to institute treatment with a schizontocide of more certain efficacy. At present, there is available for this purpose an extremely limited imperfect range of antimalarials. The list that follows is divided : (a) some patients are amenable to suprevised treatment over a period of 14 or more days, while (b) other only be accessible for a day or two, undersirable though this may be. No attempt is made to recommend a particular course, as the choice may depend on local circumstances and preference, but the conrses listed are representative of the 'most successfull used in the past 3 years among patients infected naturlly. The doses given relate to non-immune adults, and where multiple should be administered in3 or 4 parts during the 24 hour speriod.

(a) In patients treated under supervision for 2 or more weeks, three types of courses, some having variations but all based on quinine given for 14 days, may be listed.

(b) Quinine sulfate 2 gm daily for 14 days (if cerebral slowly administer quinine dihydrochloride intravenously 0.6 gm every 8 hours for a maximum of 3 doses ; but if oliguria reduce dosages whether oral or intravenous ; when 10 not 14 days courses are used, the recrudescence rate is greater).

2. Qunine sulfate 2 gm daily for 14 days, together with pyrimethamine 50 mg daily on Days 1-3, together with (a) DDS 25 mg daily on Days 7-35, or (b) sulfisoxazole or sulfadiazine 2 gm daily on Days 1-6.

3. Quine sulfate 2 gm daily for 14 days, together with sulfalence (sulfamethoxypyrazine) 1 gm Day 1; if recrudescence occurs later, which is very rare, the course may be repeated but with sulfalene increased to 1 gm given on Day 1, 5 and 10. Obviously the selection of this spacing is arbitrary, and with experience may be modified.

(b) Cases available only briefly for treatment ; several course, with a duration of from ane to seven days, are available. In general, they are less satisfactoro than the quinine courses listed above, either because of a greater tendency for the infection to recrudence subsequently (courses 1-3), or because the immediate schizontocidal effect is slow (courses 1, 3 & 4).

1. Single dose cure : pyrimethamine 50 mg (1 mg/kg), together with (a) sulformethoxine (sulfadoxine) 1 gm (15-20 mg/kg) or (b) sulfatene 2 gm (30 mg/kg) or (c) DDS 200 mg.

2. 3 days course : trimethoprin 1.5 gm, with sulfalene 1.0 gm. daily for 3 days.

3. 5 day course : (a) pyrimethamine 50 mg daily x 3 days with sulfadiazine 2 gm daily x 5 days or (b) pyrimethamine 50 mg single dose with DDS 100 mg daily x 5 days.

4. 7 days course : tetracyclines given daily for 7 days provide radical cure of falciparum malaria but parasite clearance is so slow that the more rapidly schizontocidal action of quinine is desirable for the beginning of the course.

Sub Centre ..... District.....
PHC..... S. No. .....

INDEX CARD

Area..... House No.....
F. F. No.....

Family Members with age & Sex [Start with head]

1.....
2.....
3.....
4.....

Sub-Centre ... ... District ... .
PHC..... .....

HOUSE VISIT INDEX CARD

1. Block .... 2. House No... ....
3. F. F. No ..... 4.
5. Name of Wife..... 6. Name of Husband.....

Dates of Visits

Plan of Visit	Date Visit	Remarks	Pan of Visit	Date of Visit	Remarks

TODDLER CARD POLIO AND TRIPLE ANTIGEN

1st Booster
2nd Booster
3rd Booster

Sub-Centre ....
Primary Health Centre.....
Date of first visit ....
Becomes Toddler on .....

District..... ... ...
Year... .....
No.....

Name... .... Caste..... ...Sex.....Date of Birth..... Father's Name.....
Occupation & wages ... Health... .....Mother's Name... ...Occupation & wages..... Health... .....
Literacy.. .... Address .... Hom. Province .....

Method of F. P. accepted :—Condom Diaphram & Jelly I. U. C. D. oral Sterlisation.

Condition at 1 year..... Weight.....Height .....Teeth..... .. Stands.. ..... Walks .....Talks .....
Vaccination... ... ...Immunisation Diptheria... ... Whooping Cough/Tetanus.
Mantaux test .. ..B.C.G. .. .. Diet Milk ... ... Cereals ... Vegetable .. Others ...

Condition at 2 years———Weight———Height———Walks——Talks———Teeth———Bladder Control
Day
Night Diet————Booster————Dose— ———Triple Antigen————Polio Vaccine————

Condition at 3 years———Weight————Height————Revaccination————Nursery School———
Diet————

Date	Age		Weight		Circumstance of Head	Notes
	Yrs.	Month	lbs	ozs		

Date	Age		Weight		Notes	Advice
	Yrs.	Month	lb.	ozs.		

ANTENATAL CARD

Card No———— F. F. No.————
Name———— Husbands Name————
Address————
House No.————
Head of the family———— Age at Marriage————
Age———— Due Date————
L.M P.———— Parity————
Obst History————

S, No.	Years ago	Nature of delivery	Alive/Dead Cause of death Alive	D	Cause	Attended ANC Yes	No	Where

General condition—
Height
Teeth
Breasts
Vaginal discharge
Heart
Lungs
Antenatal Notes :—

Immunisation status
Tetanus I II III
Date

Lab. Investigations
V, D. *R.* Positive/Negative

Date	Wt.	Urine	B.P.	Hb.	Ht. of Ut.	F. H. S.	Position	Remarks

Delivery Notes :

Labour started at———— on————
Delivered at———— on————
Birth wt.———— on————

Sex————
Condition at birth————
Coducted by————

Sub-Centre————
Prim. Health Centre———— District————

INDIVIDUAL HEALTH CARRD

H. No.———— F. F. No.————
Name———— Age & Sex———— Marital Status————

Occupation
Educational status
Past History

Relationship to the head————

Date	Medical Examination (give positive findings only)	Diagnosis	Lab. Investigations

Date	Notes	Treatment

CONTINUATION CARD

Name———— Year————
REVISITS No.————

Date	Age	Weight	Notes	Advice

INFANT CARD SUB - CENTRE H. D. 21

PRIMARY HEALTH CENTRE

DISTRICT.....

Date of 1st visit———— Year————

No.

Name———— Religion———— Sex———— Date of Birth————

Father's Name————Address———— Occ. Income————

Mother's Name———— Occ. & Wages————

Birth order———— Living order————

Home condition———— Mother health———— Literacy————

Confinement————Attendent————Maturity———— S.T.S.————

Vaccination———— Immunisation Whooping Cough/Diptherial/Tetanus————

Antenatal good/fair/poor.

MANTOUK B. C. G.

Milestones	Age in Week	Milestone	Age in weeks
Take notice Follows Objects		Central Upper Incisor	
Smiles		Lateral Premolar	
Holds Head		Canine	
Holds Object		Crawls	
Turns Over		Stands	
Sits		Ant font Closed	
Central Lower Inclsor		Single words Walks	

At birth	Feeding	Weight	Length	Circum head	Crown
0— 1 month					
1— 3 months					
4— 6 ,,					
7— 9 ,,					
10—12 ,,					

Date	Age	Weight	Notes

FAMILY LIST

S. No.	Name	Date of Birth	Sex	Age	Relation to Head	Educational Level	Occupation with approximate income	Health Need of the Family					
								Date	I	T	P	F.P.	S Care

No. of

I Infants
T Toddlers
P Pregnant Lady

F.P.—Need Family Planning
S.C.— ,, Special Care

IMMUNIZATION STATUS

Pre-Natal Tetanus Toxoid			Smallpox B.C.G.	Triple Vaccine			Measles	T.A.B.	Booster Doses						Anti-Cholera Inoc.	Remarks
1 dose 16-20 weeks	II dose 20-24 weeks	III dose 36-38 weeks	Between 3-9 month	I	II	III		5-6 yrs	Triple Antigen 18-24 M.	T. T. 10 yrs. / 16 yrs.	Dipth. Teta-nus 5-6 yr.	Polio 18-24 M.	T. A. B. 10 yrs. / 16 yrs.			

Total No. of living Rooms
Type of house, kacha, pucca own, rented duration of stay–

Separate Kitchen	Yes	No
L & V adequate	Yes	No
Sanitary Laterine	Yes	No
Using Public Laterine	Yes	No
Water tap present in the house	Yes	No
Water & Tap in the Street	Yes	No
Hand Pump	Yes	No

Kitchen Garden
Type of family

IMMUNIZATION RECORD OF CHILD

Sr. No. _____

Name of the Unit _____

Date of first visit _____

Name of child _____

Sex : _____ Date of birth _____

Age : _____

Father's name _____

Address _____

_____

VACCINATION	DATE
B.C.G.	_____
D.P.T. (1st Dose)	_____
D.P.T. (2nd Dose)	_____
D.P.T. (3rd Dose)	_____
Smallpox	_____
Polio (1st Dose)	_____

DAILY IMMUNIZATION RECORD

Name of Unit : _____

Name of Workers: _____

Date : _____

VACCINATION PERFORMANCE : Age (in years)

0-1, 1-3, 3-5

Vaccine :

B.C.G. :

Smallpox :

D.P.T. (1st Dose) :

D.P.T. (2nd Dose) :

D.P.T. (3rd Dose) :

Polio (1st Dose) :

Polio (2nd Dose) :

Polio (3rd Dose) :

Booster :

Other :

Ampoules or Vials of vaccine used with batch No.

_____

MONTHLY REPORT OF EXPANDED PROGRAMME OF IMMUNIZATION

Name of Basic Reporting Unit : _____

Month : _____ Year : _____

A. Surveillance

DISEASES	CASES	DEATHS
Diphtheria :		
Whooping Cough :		
Tetanus :		
Measles :		
Tuberculosis :		
Poliomyelitis :		

VACCINATION PERFORMANCE (number) :

Smallpox :
B.C.G. :
D.P.T. (1st) :
D.P.T. (2nd) :
D.P.T. (3rd) :
Polio (1st) :
Polio (2nd) :
Polio (3rd) :
Booster :

_____

_____

Other :

_____

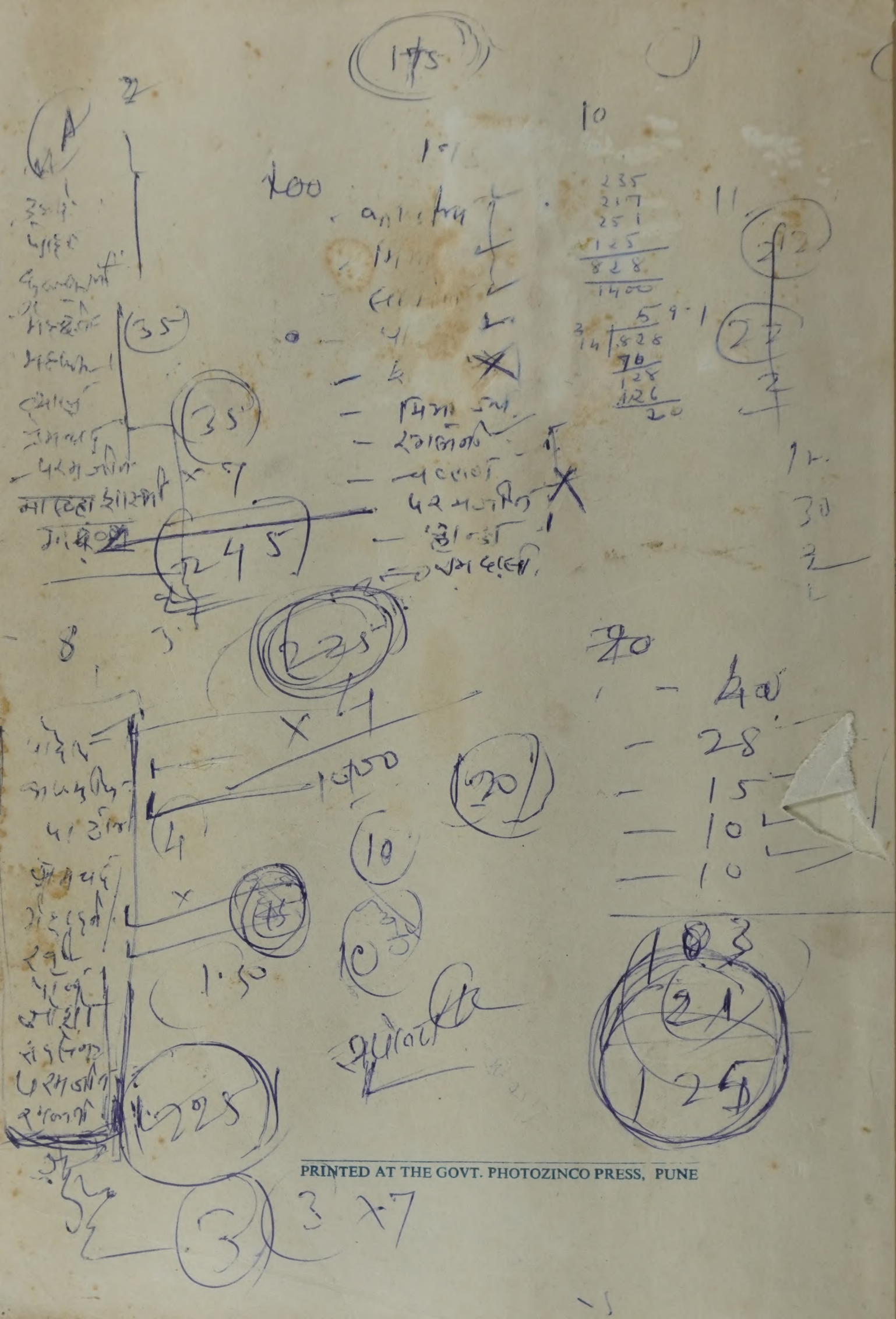
C. Condition of Refrigerator :

REGISTER OF IMMUNIZATION

Card Sr.No.	Name of child	Age	Village M./Ne.	Date of Vaccination					
				BCG	Smallpox	DPT (1)	DPT (II)	DPT(III)	Booster

e of Visit _____ Advice _____ Next date of visit _____

Was the mother of child vaccinated with Tetanus Toxoid during pregnancy ? Give particulars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